

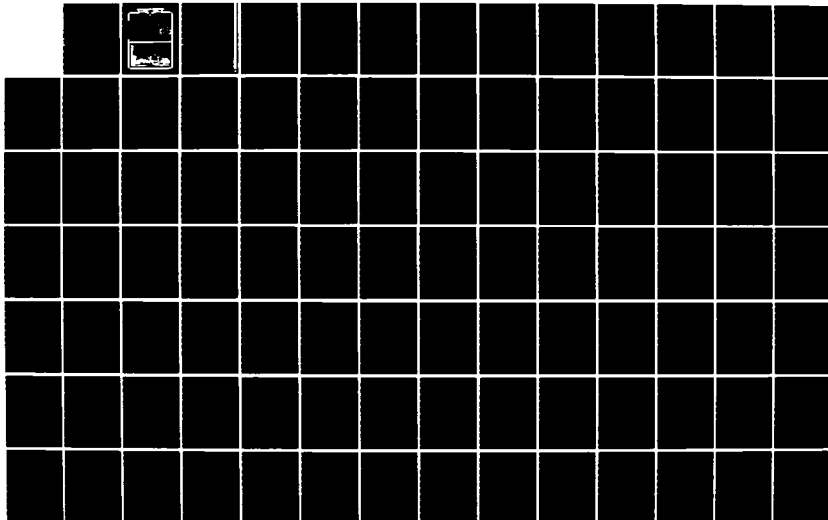
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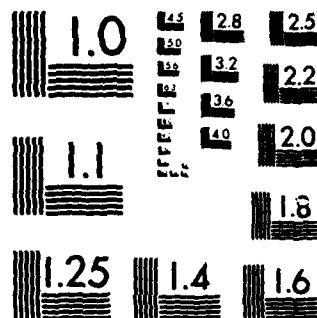
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BROOKE ARMY MEDICAL CENTER FORT SAM HOUSTON, TEXAS 78234



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Detail Summary Sheet

Date: 18 Oct 85 Proj No: A-1-84 Status: Ongoing
 Title: A Pilot Study Using the HeNe Laser to Enhance Healing of Hematomas.

Start Date 6 Feb 84	Est Comp Date:
Principal Investigator Debra J. Krikorian, Ph.D., CPT, MS	Facility Brooke Army Medical Center
Dept/Svc Department of Clinical Investigation	Associate Investigators: Steven Stratton, Ph.D., CPT, AMS Terry Nemmers, M.P.T., M.S., MAJ, AMS Michael Hartshorne, M.D., MAJ, MC Wendy Blomgren, SP5
Key Words: Hematoma Laser, HeNe	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 900.00
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To test the effectiveness of treating severe hematomas with The Helium Neo Laser (HeNe Laser).

Technical Approach: The right lateral thighs of rats were gravitationally traumatized yielding full thickness hematomas. Experimental animals were treated with an HeNe laser (632.8 nm) over a 10 day period and their lesions compared to those of untreated animals. Hematomas were visualized histologically and by ⁶⁷Ga gamma scans.

Progress: "Healing curves" based on ⁶⁷Ga uptake ratios in the traumatized vs non-traumatized leg reveal no statistically significant enhancement of healing with HeNe laser therapy. Histological evaluations have proven extremely difficult to tabulate but subjective reviews imply no difference in the healing patterns between control and treated legs. Furthermore, objective data analysis is desired if funds are available for computerized morphometric types of analysis.

Detail Summary Sheet

Date: 18 Oct 85 Proj No: A-3-84 Status: Completed
 Title: Bladder Surface Mucin - Impact on Implantation of Transitional Cell Carcinoma II: Use of Standard Urologic Irrigants for Mucin Removal.

Start Date 13 Mar 84	Est Comp Date:
Principal Investigator Ian M. Thompson, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators: William Gregory, SP5 Wendy Blomgren, SP5 Edward J. Shumski, M.D., LTC, MC C. Ritchie Spence, M.D., COL, MC
Key Words: Carcinoma, transitional cell Bladder surface mucin	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To determine if presence of bladder surface mucin and/or artificial reconstitution thereof prevents implantation of transitional cell carcinoma of the bladder after mucin removal with standard urologic intravesical irrigants.

Technical Approach: Animals are randomized to receive either heparin prophylaxis or saline control to attempt to prevent adherence and growth of intravesically-implanted transitional cell carcinoma.

Progress: This study was performed in duplicate. Although a previous study suggested that mucin reconstitution may prevent implantation of transitional cell carcinoma, this study was unable to prove such an association.

Detail Summary Sheet

Date: 18 Oct 54 Proj No: A-4-84 Status: Ongoing
 Title: Radiation Therapy and Synergism with Chemotherapy for Treatment of Transitional Cell Carcinoma of the Bladder.

Start Date 3 May 84	Est Comp Date:
Principal Investigator Ian M. Thompson, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators: William Gregory, SP5 Wendy Blomgren, SP5 Clayton L. Hadick, D.V.M., CPT, VC Madahava Baikadi, M.D., MAJ, MC C. Ritchie Spence, M.D., COL, MC
Key Words: Carcinoma, transitional cell	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 714.00
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To investigate the therapeutic effects of external beam radiotherapy and its possible synergism with chemotherapeutic agents in the therapy of murine transitional cell carcinoma.

Technical Approach: Two separate studies will be performed which will study the effect of radiation therapy for post-excisional treatment of transitional cell carcinoma.

The second study will investigate the effect of radio-sensitizers and cytoxan in the treatment of established murine transitional cell carcinoma.

Progress: This is a two-part study. The first part, employing cisplatin, radiation therapy, a combination of both, and control animals demonstrated that radiated animals had a lesser degree of mortality than did any of the other treatment arms. The second part of the study will begin shortly.

Detail Summary Sheet

Date: 31 Oct 84 Proj No: A-5-84 Status: Completed
 Title: Effect of Synthetic Sutures on Pelvic or Intraperitoneal Adhesions.

Start Date 5 Jun 84	Est Comp Date:
Principal Investigator Richard K. Cardenas, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Obstetrics-Gynecology	Associate Investigators: Clayton L. Hadick, D.V.M., CPT, VC
Key Words: Adhesions, pelvic Adhesions, intraperitoneal	William Gregory, SPT5 Wendy Blomgren, SP5
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To study the incidence of pelvic and intraperitoneal adhesions when using synthetic sutures on peritoneal closure.

Technical Approach: Forty rabbits were used for this study. Animals were divided into four groups. One group was reperitonealized using braided polyglycolic suture, one was reperitonealized using chromic suture, one was repaired with PDS suture, and the final group had no sutures used on the peritoneum.

Progress: There was no difference seen as far as the type of suture used and the incidence of pelvic and intraperitoneal adhesions.

Detail Summary Sheet

Date: 29 Aug 85 Proj No: A-6-84 Status: Ongoing
 Title: Development of a Primate Model of Carcinogen-Induced Transitional Cell Carcinoma.

Start Date 5 Jun 84	Est Comp Date:
Principal Investigator Ian M. Thompson, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators:
Key Words: Carcinoma, transitional cell	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____ Results _____	

Objective(s): To develop a model of induced transitional cell carcinoma in the non-human primate.

Technical Approach: Transitional cell induction will be performed via oral carcinogen feeding in non-human primates. The implications of the study are tremendous with an ability to perfect a model which would allow controlled evaluation of surgical, chemotherapeutic, and radiation therapeutic modalities for the treatment of transitional cell carcinoma.

Progress: This study will start as soon as funding is approved.

Detail Summary Sheet

Date: 16 Jun 85 Proj No: A-8-84 Status: Completed
 Title: Intraarterial Infusion of Cisplatin in Combination with Hemoperfusion -
 An Experimental Approach to Advanced Bladder Cancer.

Start Date 21 Aug 84	Est Comp Date:
Principal Investigator James B. Rounder, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators: Ian M. Thompson, M.D., CPT, MC Clayton L. Hadick, D.V.M., CPT, VC Wendy Blomgren, SP5 Frederic A. Lombardo, Ph.D., CPT, MSC C. Ritchie Spence, M.D., COL, MC
Key Words: Bladder cancer	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To determine if intra-arterial infusion of Cisplatin (CDDP) in conjunction with direct hemoperfusion (DHP) will deliver a high concentration of anticancer drug to the bladder while reducing systemic levels of the drug.

Technical Approach: An experimental pig model was developed to investigate the feasibility of intra-arterial infusion of Cisplatin in combination with direct hemoperfusion (DHP). The basic concept was to infuse high dose Cisplatin into the plevic arterial system to achieve high tissue levels within the bladder and at the same time remove Cisplatin from the circulation by DHP. There were four experimental groups with all but one group employing DHP with increasing infusion doses of Cisplatin. Blood, bladder tissue, urine and ultrafiltrate from the DHP unit were assayed for platinum levels.

Progress: High dose intra-arterial infusion of Cisplatin was found to deliver high concentration of Cisplatin to the bladder and tissue levels of platinum were not compromised by the utilization of DHP. DHP was seen to keep serum levels of platinum at levels equivalent to serum levels seen at lower doses not utilizing DHP. The therapeutic efficacy and reduction in side effects awaits evaluation through clinical studies.

Detail Summary Sheet

Date: 18 Oct 85 Proj No: A-9-84 Status: Ongoing
 Title: Development of an Animal Training Model of the Koch Continent Ileal Reservoir.

Start Date 21 Aug 84	Est Comp Date:
Principal Investigator Ian M. Thompson, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators: Clayton L. Hadick, D.V.M., CPT, VC Wendy Blomgren, SP5 James B. Rounder, M.D., CPT, MC Julius L. Teague, M.D., CPT, MC C. Ritchie Spence, M.D., COL, MC
Key Words: Ileal reservoir	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____ Results _____	

Objective(s): To serve as a training protocol to teach the technique of creation of a continent ileal conduit to Urology residents at BAMC.

The development of a noncanine model for the long-term observation of anatomic results of the Koch ileal conduit.

Technical Approach: Thus far, six procine subjects have undergone a randomized trial of standard sutured versus surgically stapled Koch urinary ileal conduits. Animals have been sacrificed approximately one week postoperatively.

Progress: Thus far, a number of Yorkshire Pigs have been used for creation of a Koch ileal pouch. Six animals were analyzed postoperatively for one week for ureteroileal leaks and pouch closure. A single nipple valve was noted to fail in this period, but otherwise, pouches were noted to be successful. Several other animals have been employed in terminal experiments to improve techniques of actually creating the conduit.

Detail Summary Sheet

Date: 28 Aug 85 Proj No: A-1-85 Status: Ongoing
 Title: Effects of Secondary Chronic Hypertension on the Hydrodynamics of the Aortic Pulse: A Primate Model.

Start Date 25 Mar 85	Est Comp Date:
Principal Investigator Ricky D. Latham, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Bernard J. Rubal, Ph.D. Richard Walsh, M.D. Nico Westerhof, Ph.D. Joseph P. Murgu. M.D., COL, MC
Key Words: Hypertension	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: n/a	
Total Number of Subjects Enrolled to Date: n/a	
Date of Periodic Review	Results

Objective(s): 1) Study the effects of chronic hypertension in a primate population on arterial dynamics compared to age-sex matched controls.

2) Determine specificity and sensitivity of arterial dynamic parameters to assess the resistive and capacitive components of hypertension.

3) Assess the accuracy of in vivo catheterization techniques to predict directly measured central aortic compliance.

4) Evaluate the differences of hydrodynamic variables between in vivo and in vitro states.

Technical Approach: In vivo catheterization with 6-sensor and flow catheter simultaneous pressure/cine v-grams and aortograms at low blood pressure, control and hypertensive pressures were done. Aorta was occluded at three pressure levels at various sites. In vitro study was done in sink table mock circulatory system using aortas from necropsy. Sine/wave spike stimuli were used.

Progress: Six control baboons and five hypertensive baboons were found and in vivo and in vitro data collected. Data analysis is in progress.

Detail Summary Sheet

Date: 21 Oct 85 Proj No: A-2-85 Status: Ongoing
 Title: LASER Therapy for Coronary Atherosclerosis in the Adult Baboon

Start Date 16 May 85	Est Comp Date:
Principal Investigator Richard A. Schatz, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Joseph P. Murgo, M.D., COL, MC Henry McGill, M.D. Dee Carey, D.V.M.
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review n/a	Results _____

Objective(s): 1) To identify which members of a population of adult baboons have developed significant coronary artery disease as a result of exposure to a highly atherogenic diet and experimentally-induced intimal disruption.

2) To identify the appropriate techniques of angiography and LASER delivery and manipulation that result in selective destruction of atherosclerotic plaques without damaging the vascular intima or media.

Technical Approach: In Phase I, we hope to identify which animals of a large baboon population have developed significant atherosclerosis, having been fed a highly-atherogenic diet using standard cardiac catheterization techniques. Phase II includes LASER vaporization of the plaques developed through phase I.

Progress: This is a new study. No data are available at this time.

Detail Summary Sheet

Date: 21 Oct 85 Proj No: A-3-85 Status: Ongoing
 Title: Helium-Neon (HeNe) Laser Treatment of Full Thickness Burns

Start Date 7 Aug 85	Est Comp Date:
Principal Investigator Debra J. Krikorian, Ph.D., CPT, MS	Facility Brooke Army Medical Center
Dept/Svc Department of Clinical Investigation	Associate Investigators: Michael J. Hartshorne, M.D., MAJ, MC Gene Hubbard, D.V.M., LTC, VC
Key Words: Laser	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review n/a	Results _____

Objective(s): To test the effectiveness of treating full thickness burns with a Helium Neon Laser (HeNe Laser).

Technical Approach: Forty male rats will be utilized for this study. Full thickness burns will be administered bilaterally on the lateral thighs. The animals will then be lased on one leg over the entire surface of the burn for four minutes. The animals will then be divided into two subgroups for evaluation by Technetium 99m-pyrophosphate imaging.

Progress: This is a new study. No reportable data are available at this time.

Detail Summary Sheet

Date: 21 Oct 85 Proj No: A-4-85 Status: Ongoing
 Title: Evaluation of the Role of Angioscopy as a Tool for Intravascular Surgery and the Study of the Cardiovascular System

Start Date 27 Sep 85	Est Comp Date:
Principal Investigator Bernard J. Rubal, Ph.D.	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Cardiology	Associate Investigators: Ricky D. Latham, M.D., MAJ, MC H. Richey, M.D., MAJ, MC
Key Words: Cardiovascular system	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review n/a	Results _____

Objective(s): To develop a percutaneous technique for direct intravascular visualization of the heart and vessels.

Technical Approach: In vivo examination of cardiovascular structures will be attempted with fiberoptic techniques developed in the postmortem and isolated heart-lung preparations in 20 animals. Angioscopy will be performed while simultaneously recording high-fidelity hemodynamic data and echocardiograms. Ten acute and ten chronic experiments will be performed.

Progress: This is a new study.

Detail Summary Sheet

Date: 21 Oct 85 Proj No: A-5-85 Status: Ongoing
 Title: Hyperfractionated Radiotherapy for Murine Transitional Cell Carcinoma

Start Date 27 Sep 85	Est Comp Date:
Principal Investigator Ian M. Thompson, M.D., CPT, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Surgery/Urology	Associate Investigators: Madahava Baikadi, M.D., MAJ, MC John Berchmans, M.D. William Bice, Ph.D., CPT, MS Michael Sarosdy, M.D. C. Ritchie Spence, M.D., COL, MC
Key Words: Carcinoma, transitional cell	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To determine the efficacy of hyperfractionated radiotherapy in comparison to standard daily radiotherapy fractions.

Technical Approach: Animals will be anesthetized and 0.1 cc of tumor suspension injected subcutaneously. Animals will be followed until 90 animals have developed tumors. Animals with equal tumor volumes will be randomly assigned to three groups. The control group will be followed until all animals have expired of their tumor burden. The radiotherapy group will receive 4000 rad directed to tumor sites via radiotherapy. The hyperfractionation radiotherapy group will receive 4000 rad directed to tumor sites in a manner identical to the radiotherapy group with the exception that doses will be halved and given twice daily, approximately 4 hours apart. During treatment of all groups, tumors will be measured three times a week in two dimensions and volumes calculated.

Progress: This is a new study. No reportable data are available.

Detail Summary Sheet

Date: 17 Sep 85 Proj No: PVSG 12 Status: Ongoing
 Title: Hydroxyurea in Thrombosis.

Start Date FY 80	Est Comp Date:
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators:
Key Words: Thrombosis	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	
Total Number of Subjects Enrolled to Date: 6	
Date of Periodic Review	Results

Objective(s): To evaluate the efficacy of hydroxyurea in preventing and controlling the symptoms of thrombosis and bleeding with 1) the clinical entity primary thrombocytopenia, 2) those patients with myelofibrosis-myeloid metaplasia with elevated platelet counts, and 3) those patients with unclassified myeloproliferative disease with elevated platelet counts.

Technical Approach: In order to be eligible for entry on this study, the patient must meet the following criteria: 1) Absence of Philadelphia chromosome, 2) absence of an increased red cell mass, 3) bone marrow which shows marked megakaryocytic hyperplasia and abundant platelet clumps, 4) thrombosis not secondary to some identifiable cause, and 5) must not have had a pre-existing cancer, other than skin cancer.

Therapy will follow the schema outlined in the study protocol.

Progress: Six patients remain on the study and are doing well.

Detail Summary Sheet

Date: 1 Apr 85 Proj No: SWOG 7804 Status: Ongoing
 Title: Adjuvant Chemotherapy with 5-Fluorouracil, Adriamycin, and Mitomycin-C (FAM) vs Surgery Alone for Patients with Locally Advanced Gastric Adenocarcinoma.

Start Date FY 78	Est Comp Date:
Principal Investigator James F. Boyd, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Glenn M. Mills, M.D., MAJ, MC
Key Words: Gastric adenocarcinoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 2	
Date of Periodic Review 9 November 1984	Results Continue

Objective(s): To determine the efficacy of adjuvant chemotherapy with 5-FU, Adriamycin and Mitomycin-C (FAM) on the disease-free interval and survival of patients with TNM stage-groups IB, IC, II and III gastric adenocarcinoma compared to potentially curative surgery alone.

Technical Approach: Eligible patients must have localized lesions at least extending into the submucosa and involving any of the deeper layers with the maximum allowable penetration into but not through the serosa; localized lesions extending through serosa, with or without direct extension to contiguous structures; a lesion diffusely involving the wall of the stomach with or without metastases to immediately adjacent perigastric nodes or a localized lesion of any depth with metastases to perigastric nodes in the immediate vicinity; a localized or diffuse lesion with metastases to perigastric nodes distant from primary.

Therapy will follow the schema outlined in the study protocol.

Progress: One hundred thirty-four patients are registered on this study. Only 89 patients are currently evaluable for recurrence and survival.

Detail Summary Sheet

Date: 11 Sep 85 Proj No: SWOG 7808 Status: Ongoing
 Title: Combined Modality Treatment for Stages III and IV, Hodgkin's Disease - MOPP #6.

Start Date FY 79	Est Comp Date:
Principal Investigator Glenn M. Mills, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC
Key Words: Hodgkin's Disease	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 November 1984 Results Continue	

Objective(s): 1. To attempt to increase the complete remission rate induced with MOP-BAP alone utilizing involved field radiotherapy in patients with Stages III and IV Hodgkin's disease achieving a PR at the end of 6 cycles of MOP-BAP.

2. To determine if immunotherapy maintenance with levamisole or consolidation with low dose involved field radiotherapy will produce significantly longer remission durations over a no further treatment group when CR has been induced with 6 cycles of MOP-BAP in Stages III and IV Hodgkin's disease.

Technical Approach: Eligible patients must have a histological diagnosis of Hodgkin's which must be classified by the Lukes and Butler system.

Therapy will follow the schema outlined in the study protocol.

Progress: Of 32 patients who have received radiotherapy, three have relapsed (9%) in comparison with 11 of 50 (22%) who have received no radiotherapy. There is not a significant difference ($p = 0.16$).

Detail Summary Sheet

Date: 9 Apr 85	Proj No: SWOG 7827	Status: Ongoing
Title: Combined Modality Therapy for Breast Carcinoma, Phase III.		

Start Date FY 80	Est Comp Date:
Principal Investigator James F. Boyd, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Glenn M. Mills, M.D., MAJ, MC
Key Words: Breast Carcinoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 4	
Total Number of Subjects Enrolled to Date: 36	
Date of Periodic Review 9 November 1984 Results Continue	

Objective(s): 1. To compare the disease-free interval and recurrence rates in estrogen receptor positive (ER+) premenopausal patients with Stage II disease, using combination chemotherapy alone versus chemotherapy and oophorectomy.

2. To compare the disease-free interval and recurrence rates in estrogen receptor positive postmenopausal patients with Stage II disease, using combination chemotherapy plus tamoxifen versus tamoxifen alone versus combination chemotherapy alone.

3. To compare the disease-free interval and recurrence rates in all estrogen receptor negative (ER-) patients with Stage II disease using one versus two years of combination chemotherapy.

4. To compare the effect of these various adjunctive therapy programs upon the survival patterns of such patients.

5. To correlate the ER status with disease-free interval and survival.

Technical Approach: All patients must have had a radical or modified radical mastectomy with histologically proven breast cancer and with one or more pathologically proven axillary nodes. Primary neoplasm and clinically apparent axillary disease must be completely removed. Pretherapy studies must reveal no evidence of metastatic disease or involvement of the other breast. Therapy will follow the schema outlined in the study protocol.

Progress: The ER negative phase of the study has been completed. However, the ER positive components to this study need to accrue more patients. It is too early to comment on results at this time.

Detail Summary Sheet

Date: 11 Sep 85 Proj No: SWOG 7983 Status: Closed
 Title: Radiation Therapy in Combination with CCNU in Patients with Incompletely Resected Gliomas of the Brain, Grade I and II.

Start Date FY 80	Est Comp Date:
Principal Investigator James F. Boyd, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Glenn M. Mills, M.D., MAJ, MC
Key Words: Glioma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 November 1984 Results Continue	

Objective(s): 1) To compare the survival of patients with incompletely resected Grade I and II gliomas treated with radiation alone vs radiation and CCNU.

2) To compare the effectiveness of radiation therapy vs radiation therapy plus CCNU for remission induction and duration of remission.

Technical Approach: Patients with histologically confirmed primary brain tumors of the following histologic types are eligible: Astrocytoma, Grade I and II with incomplete tumor resection. Patients who have had surgery with histologic diagnosis within the previous six weeks are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: At the present time, an analysis of survival comparing radiation alone to radiation plus CCNU has radiation therapy alone demonstrating a superior survival with a p value of .001 in a two-tailed test.

Detail Summary Sheet

Date: 12 Sep 85 Proj No: SWOG 7984 Status: Ongoing
 Title: Treatment of Chronic Stage CML with Pulse, Intermittent Busulfan Therapy with or without Oral Vitamin-A, Phase III.

Start Date Nov 80	Est Comp Date:
Principal Investigator vice McCracken Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC
Key Words: Leukemia, Chronic Myelogenous	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	0
Total Number of Subjects Enrolled to Date:	1
Date of Periodic Review 9 November 1984	Results Continue

Objective(s): To determine the efficacy of standard pulse, intermittent busulfan therapy plus oral Vitamin A in prolonging the chronic phase of CML, and hence in prolonging survival.

Technical Approach: All patients with newly diagnosed chronic stage CML will be eligible for entry onto this protocol. Patients who have had prior hydroxyurea and/or leukopheresis for less than seven days after initial diagnosis are likewise eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: There is a strong possibility this protocol will close soon because it is unlikely accrual goals will be met within a reasonable time frame.

etail Summary Sheet

Date: 12 Sep 85	Proj No: SWOG 7990	Status: Ongoing
Title: Testicular Cancer Intergroup Study.		

Start Date FY 80	Est Comp Date:
Principal Investigator James F. Boyd, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Glenn M. Mills, M.D., MAJ, MC
Key Words: Testicular cancer	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 November 1984 Results Continue	

Objective(s): 1) To compare the disease-free survival and overall survival for surgery alone (with chemotherapy for relapsers) vs surgery plus early adjuvant chemotherapy in patients with resectable Stage II testicular cancer.

2) To register and follow patients with non-seminoma, non-choriocarcinoma stage I testicular cancer, to define prognostic variables which may predict recurrence in this stage group.

3) To define the difference in disease-free rates and patterns of recurrence based upon histologic subtypes and extent of disease on initial presentation.

4) To evaluate the role of marker substances such as human chorionic gonadotropin, alpha-fetoprotein, and lactic dehydrogenase in the early detection and management of recurrences in patients with stage I and stage II testicular carcinoma.

5) To evaluate the accuracy of lymphangiogram, CAT scans, and ultrasound studies for staging of retroperitoneal nodal involvement.

Technical Approach: Patients with histologically confirmed carcinoma of the testis, stage I or stage II, are eligible. Patients should enter the study between two and four weeks after lymphadenectomy.

Therapy will follow the schema outlined in the study protocol.

Progress: The study continues to show prevention of relapses in Stage II patients with chemotherapy. However, the study also continues to show good recovery and curative treatment for patients who receive chemotherapy at relapse.

Detail Summary Sheet

Date: 12 Sep 85 Proj No: SWOG 8001 Status: Ongoing
 Title: Evaluation of Two Maintenance Regimens in the Treatment of Acute Lymphoblastic Leukemia in Adults, Phase III.

Start Date FY 80	Est Comp Date:
Principal Investigator(vice McCracken) Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: James F. Boyd, M.D., LTC, MC
Key Words: Leukemia, Lymphoblastic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 2	
Date of Periodic Review 9 November 1984 Results Continue	

Objective(s): 1) To evaluate the effectiveness, as determined by the complete remission rate of the L10 protocol using, Vincristine, Prednisone, and Adriamycin for induction, followed by intensive consolidation in the treatment of acute ALL.

2) To compare the effect on remission duration and survival of two maintenance regimens: the L10 "eradication" regimen vs cyclic therapy with POMP-COAP-OPAL.

3) To determine the reproducibility of the FAB histologic classification and correlation to response to therapy of ALL in adults.

Technical Approach: Patients are eligible with the diagnosis of acute lymphoblastic leukemia who satisfy the following criteria: a) Absolute infiltration of the marrow with >50% blasts (Absolute infiltration is defined as the total blast cell percentage (%) multiplied by the bone marrow cellularity percentage divided by 100); b) If the absolute infiltrate is 30-49%, evidence of progressive disease prior to entering the study will be required.

Therapy will follow the schema outlined in the study protocol.

Progress: Groupwide, this protocol has accrued 130 evaluable patients. The complete response rate is 72%. There were 24 early deaths during induction therapy. The majority of these deaths occurred in patients over the age of 50. The overall median survival on this study at the present time is 1.5 years. Patients under the age of 20 appear to have a shorter median duration of remission than the overall group.

etail Summary Sheet

Date: 12 Apr 85	Proj No: SWOG 8006	Status: Completed
Title: Postoperative Reductive Chemotherapy for Stage III or IV Operable Epidermoid Carcinoma of the Oral Cavity, Oropharynx, Hypopharynx, or Larynx, Phase III.		
Start Date Nov 80	Est Comp Date:	
Principal Investigator James F. Boyd, M.D., LTC, MC	Facility Brooke Army Medical Center	
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Glenn M. Mills, M.D., MAJ, MC	
Key Words: Epidermoid Carcinoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	
Number of Subjects Enrolled During Reporting Period: 1		
Total Number of Subjects Enrolled to Date: 22		
Date of Periodic Review 9 November 1984		Results Continue

Objective(s): To determine the length of remission, recurrence rates, survival rates, and pattern of recurrence for patients receiving therapy utilizing surgery and postoperative radiation vs combined therapy utilizing preoperative chemotherapy, surgery, and postoperative radiation therapy in operable Stage III or IV epidermoid carcinoma of the head and neck.

Technical Approach: Patients with operable lesions will be randomized between two therapeutic programs: Arm I - combined therapy including surgery and post-operative radiation therapy; or Arm 2 - combination chemotherapy followed by surgery and radiation therapy. Patients randomized to the chemotherapy limb will receive three courses of chemotherapy consisting of cis-platinum, methotrexate, vincristine, and bleomycin.

Therapy will follow the schema outlined in the study protocol.

Progress: Patient accrual was good. The overall response of 75% and complete response rate of 29%.

Detail Summary Sheet

Date: 12 Sep 85 Proj No: SWOG 8024 Status: Ongoing
 Title: Combined Modality Therapy for Disseminated Soft Tissue Sarcomas,
 Phase II.

Start Date May 81	Est Comp Date:
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Glenn M. Mills, M.D., MAJ, MC
Key Words: Sarcoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 November 1984	Results Continue

Objective(s): 1) To compare the effectiveness of bolus administration of Adriamycin and DTIC, to continuous infusion administration of Adriamycin and DTIC, in remission induction of patients with disseminated soft tissue sarcomas.

- 2) To compare the toxicities of these two drug schedules.
- 3) To determine the feasibility on a group-wide basis of surgical excision of accessible lesions in partially responding patients.
- 4) To compare the histology of the diagnostic lesion with the histology of tumor removed from the partial responder.

Technical Approach: Patients with a biopsy confirmed diagnosis of a soft tissue sarcoma with convincing clinical or biopsy-documented evidence of metastatic disease are eligible for this study. Patients must not have received prior chemotherapy with the agents used in this study. Patients must have a life expectancy of 10 weeks, and all patients must have lesion(s) which is measurable and can be followed for tumor response.

Progress: Response rates are improving as the study progresses with the continuous infusion arm showing a lower response rate to date. Life-threatening toxicity is similar in both arms since the DTIC dose was decreased in the continuous infusion arm.

Detail Summary Sheet

Date: 27 Mar 85 Proj No: SWOG 8040/44 Status: Completed
 Title: Evaluation of Combination Chemotherapy (FAM-S) vs a Phase II Drug (AZQ) in Pancreatic Adenocarcinoma, Phase II.

Start Date 22 May 81	Est Comp Date:
Principal Investigator James F. Boyd, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Glenn M. Mills, M.D., MAJ, MC
Key Words: Adenocarcinoma, Pancreas	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	0
Total Number of Subjects Enrolled to Date:	0
Date of Periodic Review 19 November 1983	Results Continue

Objective(s): 1) To determine the response rate and survival in patients with advanced pancreatic adenocarcinoma treated with 5-FU, Adriamycin, Mitomycin-C, and Streptozotocin (FAM-S).

2) To determine further the toxicity of the FAM-S regimen.

3) To determine the activity of a Phase II drug in previously untreated patients with advanced adenocarcinoma of the pancreas by determination of response rate and duration of response and survival.

4) To determine further the toxicity of each Phase II agent.

Technical Approach: Patients with histologic confirmation of adenocarcinoma of the exocrine pancreas with distant metastases and/or those with localized disease not amenable to curative surgery or radiotherapy are eligible. All patients must have objectively measurable disease and a life expectancy of at least 10 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: Sixteen good risk patients were randomized to AZQ. No responses in these 16 patients were observed. It was concluded that AZQ has no value in the treatment of pancreatic carcinoma.

Detail Summary Sheet

Date: 12 Sep 85 Proj No: SWOG 8044 Status: Closed
 Title: Evaluation of AZQ in Pancreatic Carcinoma, Phase II.

Start Date: 11 Feb 83	Est Comp Date: Unknown
Principal Investigator: Glenn M. Mills, M.D., MAJ, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC
Key Words: Carcinoma, Pancreas	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 3	
Date of Periodic Review: _____	Results: _____

Objective(s): 1) To determine the antitumor activity of AZQ in pancreatic carcinoma.

2) To further determine the nature and extent of AZQ in a Phase II study.

Technical Approach: Patients with histologic confirmation of adenocarcinoma of the exocrine pancreas with distant metastases and/or those with localized disease not amenable to curative surgery or radiotherapy are eligible. All patients must have objectively measurable disease and a life expectancy of at least 10 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: Groupwise, eighteen patients fully evaluable for response have been entered on this protocol with no complete or partial remissions identified. This study indicated no significant antitumor activity for AZQ in pancreatic cancer.

Detail Summary Sheet

Date: 13 Sep 85 Proj No: SWOG 8049 Status: Ongoing
 Title: The Treatment of Resected, Poor Risk Prognosis Malignant Melanoma:
 Stage I - Surgical Excision vs Surgical Excision + Vitamin A, Phase III.

Start Date 9 Oct 81	Est Comp Date:
Principal Investigator Glenn M. Mills. M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC
Key Words: Malignant Melanoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 9 November 1984 Results Continue	

Objective(s): 1) To determine the efficacy of surgical excision or surgical excision plus vitamin A in preventing the recurrence of high-risk, Stage I malignant melanoma by determination of remission or disease-free interval.

2) To determine the immunocompetence of patients with malignant melanoma and to determine the influence of vitamin A upon that immunocompetence.

Technical Approach: All patients with a histologically-confirmed diagnosis of high-risk Stage I malignant melanoma who have not been previously treated with chemotherapy, radiation therapy or immunotherapy are eligible. All patients must have had a wide local excision of the primary lesion.

Therapy will follow the schema outlined in the study protocol.

Progress: Ninety-seven percent of the patients receiving Vitamin A had none to moderate toxicity with only 3% having severe. Stage II melanoma patients will now be placed on this study.

Detail Summary Sheet

Date: 9 Sep 85 Proj No: SWOG 8092 Status: Completed
 Title: Human Tumor Stem Cell Assay Directed Chemotherapy for Ovarian Cancer.

Start Date 11 May 81	Est Comp Date:
Principal Investigator James F. Boyd, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Glenn M. Mills, M.D., MAJ, MC
Key Words: Cancer, Ovarian Cell, Human Tumor Stem	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 November 1984 Results Continue	

Objective(s): 1) To utilize the human tumor cloning assay to select single agent chemotherapy for patients with epithelial-type ovarian cancer, refractory to standard therapy.

2) To determine if the human tumor cloning system can be utilized to select individual patient's therapy in a cooperative group setting.

Technical Approach: Eligible patients must have a pathological diagnosis of epithelial-type ovarian cancer in pleural or peritoneal fluid. Patients should have measurable disease and a life expectancy of at least three months.

Progress: Fifty-nine percent of the submitted specimens formed greater than 30 colonies per plate with a median number of colonies for a control plate of 52. The percent true positive rate for the assay with respect to the single agent correlations was 38% and for combination therapy was 60% with an overall predictive accuracy for response of 47%. The overall percent true negative for both single agent and combination agent therapy was 86%.

Detail Summary Sheet

Date: 13 Sep 85 Proj No: SWOG 8094 Status: Ongoing
 Title: Radiotherapy with and Without Chemotherapy for Malignant Mesothelioma
 Localized to One Hemithorax, Phase III.

Start Date 22 May 81	Est Comp Date:
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC
Key Words: Mesothelioma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	0
Total Number of Subjects Enrolled to Date:	3
Date of Periodic Review 9 November 1984	Results Continue

Objective(s): 1) To evaluate in a randomized prospective manner, the efficacy of Adriamycin in improving the disease-free interval in patients who will receive hemithoracic radiotherapy for Stage I pleural mesothelioma.

2) To further define prospectively the efficacy of radiotherapy to the involved hemithorax in patients with pleural mesothelioma.

Technical Approach: Eligible patients will have histologically confirmed malignant mesothelioma of the pleural cavity. Patients with measurable disease or evaluable disease as well as those in whom all gross disease has been resected will be eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: Groupwide, no significant new toxicity has been noted.

Detail Summary Sheet

Date: 11 Sep 85 Proj No: SWOG 8102 Status: Ongoing
 Title: Whole Brain Irradiation and Intrathecal Methotrexate in the Treatment of Solid Tumor Leptomeningeal Metastases.

Start Date 12 Feb 82	Est Comp Date: Unknown
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC
Key Words: Leptomeningeal metastases	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	0
Total Number of Subjects Enrolled to Date:	0
Date of Periodic Review 9 November 1984	Results Continue

Objective(s): To determine the response rate (CR + PR) of intrathecal methotrexate and whole brain irradiation in the control of solid tumor leptomeningeal metastases.

Technical Approach: All patients must have cerebrospinal fluid which is cytologically positive for malignant cells.

Therapy will follow the schema outlined in the study protocol.

Progress: Groupwise, 25 patients have been entered into this study. Of the 21 evaluable for response, 15 have had breast cancer with six showing a complete or partial response with a median duration of 3+ months and a median survival of 6+ months. The median survival of the nine non-responding breast cancer patients was 1.6 months. Three patients with melanoma, two with lung, and one with ovarian cancer failed to respond with a median survival of approximately two months.

Detail Summary Sheet

Date: 9 Apr 85 Proj No: SWOG 8104 Status: Ongoing
 Title: Treatment of Advanced Seminoma (Stage cII(N₄) + cIII) with Combined Chemotherapy and Radiation Therapy, Phase II.

Start Date May 82	Est Comp Date:
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC
Key Words: Seminoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 9 November 1984	Results Continue

Objective(s): To determine the response rate and survival patterns in patients with advanced seminoma (Stage cII (N₄) + cIII) treated with combined chemotherapy and radiation therapy.

Technical Approach: All patients with histologically proven, Stage cII (N₄) and cIII, advanced, pure or anaplastic testicular seminoma who have had no prior chemotherapy or radiation therapy are eligible. Patients must have no other evidence of malignant disease.

Therapy will follow the schema outlined in the study protocol.

Progress: Groupwide, 21 patients have been entered on the study, 18 of whom are evaluable. Complete responses have been seen in 13 patients; partial responses in two.

Detail Summary Sheet

Date: 17 Sep 85	Proj No: SWOG 8107	Status: Ongoing
Title: Management of Disseminated Melanoma, Master Protocol, Phase II-III.		

Start Date 9 Jul 82	Est Comp Date:
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC
Key Words: Melanoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 3	
Date of Periodic Review 9 November 1984 Results Continue	

Objective(s): To determine the effectiveness of cranial irradiation given electively in disseminated melanoma patients with lung and/or liver metastases to prevent or delay the clinical appearance of brain metastases.

Technical Approach: Patients should have histologic proof of melanoma and a negative radiographic study of the brain. Patients must have established disseminated melanoma with lung and/or liver metastases. Patients will be randomized to Arm I (DTIC plus Actinomycin) vs. Arm II (Cisplatinum, Velban, and Bleomycin).

Therapy will follow the schema outlined in the study protocol.

Progress: The study will remain open until sufficient patient accrual has been obtained. At the first indication that the Cis-platinum combination limb is equal to or inferior to the control limb, the study will be closed. New combination chemotherapies will be piloted. If these combinations or reported combinations in the literature yield response rates of 35% or greater, they will then be used as a single limb in patients with disseminated melanoma.

Detail Summary Sheet

Date: 9 Apr 85	Proj No: SWOG 8110	Status: Ongoing
Title: Treatment of Advanced Germ Cell Neoplasms of the Testis: A Comparison of Remission Induction with Vinblastine, Bleomycin and Cis-Platinum vs Vinblastine, Cis-Platinum and VP-16; Surgical Removal of All Residual Tumor... vs. Observation		
Start Date 11 Jun 82	Est Comp Date:	
Principal Investigator James F. Boyd, M.D., LTC, MC	Facility Brooke Army Medical Center	
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Glenn M. Mills, M.D., MAJ, MC	
Key Words: Germ Cell Neoplasms Testis		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	
Number of Subjects Enrolled During Reporting Period: 3		
Total Number of Subjects Enrolled to Date: 6		
Date of Periodic Review 9 November 1984 Results Continue		

Objective(s): 1) To compare in a randomized fashion the effectiveness of the drug combination Vinblastine, Cis-Platinum, and VP-16 vs Vinblastine, Bleomycin and Cis-Platinum in the remission induction of patients with disseminated germ cell neoplasms of testicular origin.

2) To determine the role of six months maintenance chemotherapy vs observation for those patients who achieve a complete response during induction, or have a totally resected mature teratoma, in terms of relapse-free survival and overall survival.

3) To determine the role of six months maintenance chemotherapy vs observation for those patients with residual carcinoma having no evidence of disease following surgery, in terms of relapse-free survival and overall survival.

4) To document the nature and extent of the hematologic and non-hematologic side effects of the treatment modalities.

Technical Approach: Patients should have a histologically confirmed diagnosis of disseminated germ cell neoplasms of testicular origin. All patients with bulky abdominal disease (Stage cII(N₄) or Stage cIII) will be eligible for the study. Patients should have an expected survival of at least eight weeks.

Progress: Groupwide, there have been near equal remission rates for both arms. The maintenance chemotherapy arm has been closed because so few patients were being entered.

Detail Summary Sheet

Date: 8 Apr 85 Proj No: SWOG 8111 Status: Closed
 Title: The Treatment of Dissected, Poor Prognosis Malignant Melanoma: Stage II
 - Surgical Excision vs Surgical Excision + Vitamin A vs Surgical Excision +
 Actinomycin-D and DTIC.

Start Date 13 May 83	Est Comp Date:
Principal Investigator James F. Boyd, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Glenn M. Mills, M.D., MAJ, MC
Key Words: Malignant Melanoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	0
Total Number of Subjects Enrolled to Date:	0
Date of Periodic Review 9 November 1984	Results Continue

Objective(s): To determine the efficacy of surgical excision plus vitamin A, and surgical excision plus combination chemotherapy (Actinomycin-D and DTIC) in preventing the recurrence of Stage II malignant melanoma by the determination of remission duration or disease-free interval.

Technical Approach: All patients must have a histologically confirmed diagnosis of lymph node melanoma and complete and adequate surgical excision of all residual disease. Patients with completely resected mucosal melanoma or first recurrence will be eligible, but will be stratified separately at the time of registration. All patients must be randomized and treatment begun within six weeks of the lymph node resection.

Therapy will follow the schema outlined in the study protocol.

Progress: This study was closed due to poor patient accrual.

Detail Summary Sheet

Date: 9 Apr 85 Proj No: SWOG 8118 Status: Closed
 Title: Evaluation of Bisantrane Hydrochloride in Refractory Malignant Melanoma, Phase II.

Start Date 9 Apr 82	Est Comp Date:
Principal Investigator James F. Boyd, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Glenn M. Mills, M.D., MAJ, MC
Key Words: Malignant Melanoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	0
Total Number of Subjects Enrolled to Date:	1
Date of Periodic Review 9 November 1984	Results Continue

Objective(s): 1) To determine the response rate and response duration of malignant melanoma treated with bisantrene hydrochloride used in a single dose, every three-week schedule.

2) To define the qualitative and quantitative toxicities of bisantrene administered in a Phase II study.

Technical Approach: All patients must have a pathologically verified histologic diagnosis of melanoma. Bisantrane is intended for therapy of patients who have had prior exposure to, and progression of disease on, protocols of higher priority. Patients must have measurable disease.

Therapy will follow the schema outlined in the study protocol.

Progress: The study was closed due to lack of response.

Detail Summary Sheet

Date: 8 Mar 85 Proj No: SWOG 8119 Status: Completed
 Title: Evaluation of Bisantrane Hydrochloride in Hepatoma.

Start Date 9 Apr 82	Est Comp Date:
Principal Investigator James F. Boyd, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Glenn M. Mills, M.D., MAJ, MC
Key Words: Hepatoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 18 November 1984 Results Continue	

Objective(s): 1) To determine the response rate and response duration of hepatomas treated with bisantrene hydrochloride used in a single dose, every three-week schedule.

2) To define the qualitative and quantitative toxicities of bisantrene administration in a Phase II study.

Technical Approach: All patients must have a pathologically verified histologic diagnosis of hepatoma. Bisantrane is intended as therapy of patients with extensive disease or those patients not eligible or relapsing on protocols of higher priority. Patients must have measurable disease.

Therapy will follow the schema outlined in the study protocol.

Progress: Groupwide, twenty patients were entered into this study. No objective responses were observed. Bisantrane appears to be inactive in this setting.

Detail Summary Sheet

Date: 18 Sep 85 Proj No: SWOG 8122 Status: Completed
 Title: Combined Modality Treatment of Extensive Small Cell Lung Cancer,
 Phase III.

Start Date 14 May 82	Est Comp Date:
Principal Investigator James F. Boyd, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Glenn M. Mills, M.D., MAJ, MC
Key Words: Small Cell Lung Cancer	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	0
Total Number of Subjects Enrolled to Date:	10
Date of Periodic Review 9 November 1984	Results Continue

Objective(s): 1) To compare the response rate and duration of a new induction program (multiple alkylating agents plus Vincristine), with emphasis on complete response, to the combination of Vincristine, Adriamycin, and Cyclophosphamide in the treatment of extensive small cell lung cancer.

2) To examine the effect of radiation consolidation on relapse in the chest and liver in patients without widespread skeletal disease.

3) To assess qualitative and quantitative toxicity of this combined modality approach.

4) To perform a prospective analysis, by electron microscopy, of the available material for clinicopathologic correlation.

5) To evaluate the effectiveness of a more aggressive radiation therapy approach to clinically evident brain metastases.

6) To evaluate the impact of chest radiation therapy following relapse as to the duration of response and survival.

7) To improve survival and the quality of life in patients with extensive small cell lung cancer.

Technical Approach: All patients with extensive small cell carcinoma of the lung are eligible for entry onto this study. Patients must not have had prior treatment with chemotherapy or radiation therapy.

Therapy will follow the schema outlined in the study protocol.

Progress: The study has been closed to entry of new patients. The value of multiple local-field "consolidation" x-ray therapy after chemotherapy was essentially negative.

Detail Summary Sheet

Date: 18 Sep 85 Proj No: SWOG 8124/5/6 Status: Ongoing
 Title: Treatment of Acute Non-Lymphocytic Leukemia with Conventional Induction, Consolidation Chemotherapy: Maintenance with Chemotherapy vs Bone Marrow Transplantation Following Total Body Irradiation, Phase III.

Start Date 12 Nov 82	Est Comp Date: Unknown
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC
Key Words: Acute non-lymphocytic leukemia	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 6	
Total Number of Subjects Enrolled to Date: 6	
Date of Periodic Review	Results

Objective(s): 1) To determine the complete remission-rate with intensive induction chemotherapy in patients with acute non-lymphocytic leukemia, focusing attention on those patients over 50 years of age.

2) To compare duration of remission and survival of patients receiving maintenance with or without intensification chemotherapy versus those patients receiving an HLA identical sibling bone marrow transplant while in first remission.

3) To determine the comparative toxicity of these regimens.

4) To compare the continuous maintenance therapy and late intensification with late intensification alone.

Technical Approach: All patients with a diagnosis of acute non-lymphocytic leukemia who have not received prior therapy and who do not have initial CNS leukemia will be eligible for this study. There are no age restrictions; however, patients over the age of 50 will not be considered for bone marrow transplantation.

Progress: On the bone marrow transplant arm, 30 patients have been transplanted. Seventeen are alive and free of disease. There has been no major impact of age on the success of those patients transplanted.

Detail Summary Sheet

Date: 18 Sep 85 Proj No: SWOG 8200 Status: Ongoing
 Title: Evaluation of Vinblastine by Continuous Infusion for Advanced, Recurrent Endometrial Carcinoma, Phase II.

Start Date 14 May 82	Est Comp Date:
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC
Key Words: Endometrial Carcinoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review	Results

Objective(s): To evaluate the efficacy of a five day vinblastine infusion with respect to remission induction, remission duration, and survival duration in patients with advanced, recurrent, or Stages III and IV endometrial carcinoma refractory to prior chemotherapy.

Technical Approach: Patients with pathologically proven adenocarcinoma of adenosquamous carcinoma of the endometrium who have recurrent disease, or Stage III or IV disease no longer treatable with radiation therapy or surgery, are eligible. Patients must not have received prior chemotherapy with vinca alkaloids. Patients may have had previous chemotherapy of other types. Patients must have clinically measurable disease either by radiologic techniques or physical examination.

Therapy will follow the schema outlined in the study protocol.

Progress: Of the 29 registered patients, 16 are presentally evaluable. There have been two responders, but both may have ovarian rather than endometrial primaries. Histologic tumor sections will be reviewed to determine the origin of the primary lesions.

Detail Summary Sheet

Date: 9 Apr 85 Proj No: SWOG 8203/04 Status: Ongoing
 Title: Randomized Comparison of Adriamycin, Mitoxantrone and Bisantrone in Patients with Metastatic Breast Cancer not Previously Exposed to Intercalating Chemotherapy, Phase III.

Start Date 10 Dec 82	Est Comp Date: Unknown
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC
Key Words: Metastatic Breast Cancer Intercalating Chemotherapy	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 16	
Total Number of Subjects Enrolled to Date: 24	
Date of Periodic Review	Results

Objective(s): 1) To determine the comparative response rate, duration of response, and survival of equimyelosuppressive doses of Adriamycin, Mitoxantrone, and Bisantrone as single agents in breast cancer patients, not previously exposed to an intercalating agent, using a single dose, every-three-week regimen.

2) To determine the salvage response rate of Adriamycin, Mitoxantrone, or Bisantrone in breast cancer patients failing one of these three agents.

3) To assess the cardiotoxicity of Adriamycin, Mitoxantrone, and Bisantrone as determined by history, physical examination, and measurement of the left ventricular ejection fraction.

4) To compare the relative noncardiac toxicities of the three agents.

Technical Approach: Patients must have a pathologically verified diagnosis of breast cancer in order to be eligible for this study. Patients must have objectively measurable or evaluable lesion(s) excluding CNS metastases. Patients must not have been previously treated with Adriamycin, Mitoxantrone, or Bisantrone, but must have had only one prior chemotherapy regimen as adjuvant therapy.

Therapy will follow the schema outlined in the study protocol.

Progress: Preliminary analyses continue to show that adriamycin has a slightly higher response rate than either mitoxantrone or bisantrine, but mitoxantrone and bisantrine have less toxicity. None of the differences in response is as yet statistically significant.

etail Summary Sheet

Date: 18 Sep 85 Proj No: SWOG 8208 Status Ongoing
 Title: Trial of Chlorozotocin and 5-FU in Metastatic Islet Cell Carcinoma,
 Phase II

Start Date 11 Mar 83	Est Comp Date: Unknown
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC
Key Words: Islet cell carcinoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	0
Total Number of Subjects Enrolled to Date:	0
Date of Periodic Review	Results

Objective(s): 1) To study the response of functioning and non-functioning islet cell carcinoma to chlorozotocin (CTZ) and 5-fluorouracil (5-FU).

2) To determine the toxicity of 5-FU and CTZ when given in combination.

Technical Approach: To be eligible for this study, all patients must have biopsy-proven islet cell carcinoma not amenable to further surgical therapy; and a minimum life expectancy of greater than six weeks. All patients must have objectively measurable disease, or a significant biochemical abnormality secondary to endocrine hyperfunction specific for their islet cell tumors.

Therapy will follow the schema outlined in the study protocol.

Progress: Groupwide, 20 patients have been entered on this study. At the time of the last analysis, eight patients were evaluable for response, two having achieved partial response. These data indicated some level of activity for this combination.

Detail Summary Sheet

Date: 9 Apr 85 Proj No: SWOG 8211 Status: Closed
 Title: Evaluation of Cis-Diamminedichloroplatinum in Disseminated Gastric Adenocarcinoma, Phase II

Start Date 8 Oct 82	Est Comp Date: Unknown
Principal Investigator James F. Boyd, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Glenn M. Mills, M.D., MAJ, MC
Key Words: Gastric adenocarcinoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review	Results

Objective(s): 1) To test the response-rate of cis-diamminedichloroplatinum (DDP) in patients with disseminated and measurable adenocarcinoma of the stomach who are previously untreated.

2) To test the response-rate of cis-diamminedichloroplatinum in patients with disseminated adenocarcinoma of the stomach who are previously treated with 5-fluorouracil, Adriamycin, and Mitomycin-C (5-FAM) chemotherapy.

Technical Approach: Eligible patients must have a histologically proven gastric adenocarcinoma and be considered inoperable for cure at the time of entry on the study. Patients must have a life expectancy of six weeks or longer.

Therapy will follow the schema outlined in the study protocol.

Progress: This study was closed due to lack of patient response.

Detail Summary Sheet

Date: 18 Sep 85	Proj No: SWOG 8215	Status: Closed
Title: Comparison of Combination Chemotherapy with VP-16 and Cis-Platinum vs BCNU, Thiotepe, Vincristine and Cyclophosphamide in Patients with Small Cell Carcinoma of the Lung Who Have Failed or Relapsed Primary Chemotherapy, Phase 3		

Start Date 8 Jul 83	Est Comp Date:
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators:
Key Words: Small cell lung carcinoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review	Results

Objective(s): 1) To confirm the efficacy of combination VP-16-213 (VP-16) and Cis-diamminedichloroplatinum (Cis-Platinum) in the treatment of patients with small cell carcinoma of the lung who have failed or relapsed on first-line treatment protocols.

2) Through a randomized trial, to compare the remission rate, duration of remission, and toxicity between the combination of VP-16 plus Cis-Platinum and the combination of bis-chloroethylnitrosourea (BCNU), triethylenethiophosphoramide (Thiotepe), Vincristine (Oncovin) and Cyclophosphamide (Cytosan) in the same group of patients.

Technical Approach: For inclusion in the study, patients must have a histologically proven diagnosis of small cell carcinoma of the lung and documented relapse or progression following prior therapy. Patients must have had prior chemotherapy. All patients who have relapsed on first-line Southwest Oncology Group protocols for either extensive disease or limited disease, or who have had prior chemotherapy with other induction studies are eligible. Patients may have had prior treatment with any of the agents used in this study, but not with either of the two combinations to be employed. All patients must have a life expectancy of at least six weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: Groupwide, there are 55 patients evaluable for response to cis-platinum + VP-16, of whom 49 had no prior exposure to these agents. Only five of forty-nine (10%) had an objective response and five of thirty-nine responses to BTOC.

Detail Summary Sheet

Date: 18 Sep 85 Proj No: SWOG 8216 Status: Ongoing
 Title: Comparison of BCG Immunotherapy and Adriamycin for Superficial Bladder Cancer, Phase III.

Start Date 30 Aug 85	Est Comp Date:
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC
Key Words: Cancer, bladder	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 2	
Total Number of Subjects Enrolled to Date: 2	
Date of Periodic Review n/a	Results

Objective(s): 1) To compare the effectiveness of intravesical BCG immuno-therapy with intravesical Adriamycin chemotherapy with respect to disease-free interval and two-year recurrence rate.

2) To compare the toxicity of topical immuno-therapy and chemotherapy.

3) To obtain experience regarding disease-free interval and the recurrence rate in patients who develop tumor recurrence and are then crossed over to the alternative treatment arm.

Technical Approach: Patients with a histologically confirmed diagnosis of transitional cell carcinoma of the bladder, Stage O(P_a) and A(P₁)_m with two recurrences within the last twelve months will be eligible as well as all patients with documented carcinoma in situ (PIS) on random biopsy.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.

Detail Summary Sheet

Date: 18 Sep 85 Proj No: SWOG 8217 Status: Closed
 Title: Evaluation of Spirogermanium in Adenocarcinoma of the Prostate, Phase II

Start Date 8 Oct 82	Est Comp Date: Unknown
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators:
Key Words: Adenocarcinoma of prostate	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 2	
Total Number of Subjects Enrolled to Date: 2	
Date of Periodic Review	Results

Objective(s): 1) To determine the response rate and remission duration of adenocarcinoma of the prostate when treated with Spirogermanium, used as a 60 minute infusion in a three times weekly schedule.

2) To define the qualitative and quantitative toxicities of Spirogermanium administered in a Phase II study.

Technical Approach: All patients must have a histologically proven diagnosis of adenocarcinoma of the prostate. They must have evaluable or measurable disease and a life expectancy of at least six weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: Twenty-three patients are evaluable. There was one partial response and no complete responses.

Detail Summary Sheet

Date: 18 Sep 85 Proj No: SWOG 8219 Status: Ongoing
 Title: Evaluation of Combined or Sequential Chemo-Endocrine Therapy in Treatment of Advanced Adenocarcinoma of the Prostate, Phase III

Start Date <u>12 Nov 82</u>	Est Comp Date:
Principal Investigator <u>Glenn M. Mills, M.D., MAJ, MC</u>	Facility <u>Brooke Army Medical Center</u>
Dept/Svc <u>Department of Medicine/Oncology</u>	Associate Investigators: <u>Walter H. Harvey, D.O., MAJ, MC</u>
Key Words: <u>Adenocarcinoma of prostate</u>	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: <u>1</u>	
Total Number of Subjects Enrolled to Date: <u>6</u>	
Date of Periodic Review	Results

Objective(s): To compare the efficacy of the sequential use of endocrine therapy followed at the time of progression by cytotoxic chemotherapy (Adriamycin and cyclophosphamide) versus the combination of endocrine therapy and chemotherapy together in the treatment of advanced adenocarcinoma of the prostate by determination of the response rate, response duration, and duration of survival.

Technical Approach: All patients with histologically proven, asymptomatic or symptomatic Stage D adenocarcinoma of the prostate are eligible. Patients may not have had previous hormonal therapy or chemotherapy. They should have a life expectancy of 6 weeks or greater.

Therapy will follow the schema outlined in the study protocol.

Progress: Groupwide, 86 patients have been entered on this study of which 57 are currently evaluable. In arm I there are 28 patients and a partial response rate of 50%, complete response rate of 3%. In arm II there are 29 patients and a partial response of 59% and complete response of 7%.

Detail Summary Sheet

Date: 18 Sep 85 Proj No: SWOG 8228 Status: Ongoing
 Title: Correlation Between Progesterone Receptor and Response to Tamoxifen in Patients with Newly Diagnosed Metastatic Breast Disease, Phase II

Start Date 12 Nov 82	Est Comp Date: Unknown
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC
Key Words: Tamoxifen Breast disease	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 2	
Total Number of Subjects Enrolled to Date: 4	
Date of Periodic Review	Results

Objective(s): To define the prognostic role of progesterone receptor in patients with newly diagnosed metastatic breast disease by correlating progesterone receptor levels with objective response rates in women treated with Tamoxifen.

Technical Approach: Female patients who have new, metastatic breast carcinoma are eligible for this study. Patients who have received prior hormonal adjuvant therapy are eligible, provided that they have not failed during therapy and the therapy has been stopped for at least three months. Patients must be ER+ in order to be eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: Groupwide, one hundred and seventy-two patients have been registered on this study. Toxicity is mild and is what would be expected with patients being treated with tamoxifen.

Detail Summary Sheet

Date: 18 Sep 85 Proj No: SWOG 8229 Status: Ongoing
 Title: Combined Modality Therapy for Multiple Myeloma, VMCP-VBAP for Remission
 Induction Therapy: VMCP + Levamisole vs Sequential Half-Body Radiotherapy +
 Vincristine-Prednisone for Maintenance or Consolidation. Evaluation...Phase II

Start Date 10 Dec 82	Est Comp Date: Unknown
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC
Key Words: Multiple myeloma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 3	
Total Number of Subjects Enrolled to Date: 8	
Date of Periodic Review	Results

Objective(s): 1) To compare the effectiveness of two intermittent pulse schedules of the chemotherapy combination of Vincristine, Melphalan, Cyclophosphamide and Prednisone (VMCP) plus Vincristine, BCNU, Adriamycin and Prednisone (VBAP) (alternating versus syncopated) for the induction of remissions in previously untreated patients with multiple myeloma.

2) For patients proven to achieve remission (at least 75% tumor regression after induction), to compare the value of 12 months of chemoimmunotherapy maintenance, VMCP + Levamisole, versus a consolidation program consisting of sequential half-body radiotherapy along with Vincristine and Prednisone followed by unmaintained remission.

3) For patients who only achieve improvement (50%-74% tumor regression) on chemotherapy induction, to determine whether sequential half-body radiotherapy along with Vincristine and Prednisone will increase the remission rate (at least 75% tumor regression).

4) To determine whether sequential half-body radiotherapy along with Vincristine and Prednisone can serve as an effective form of induction therapy for patients who fail to respond to chemotherapy or suffer early relapse.

Technical Approach: Only previously untreated patients with the diagnosis of multiple myeloma are eligible. This is a first-line study and only patients without prior cytotoxic chemotherapy are eligible.

Progress: Groupwide, patient accrual has been excellent. Evaluation of response to treatment and survival on this study is extremely encouraging. In as much as all patients receive VMCP-VBAP for induction, the overall response rate and early survival are extremely encouraging.

Detail Summary Sheet

Date: 18 Sep 85 Proj No: SWOG 8231 Status: Ongoing
 Title: Chemotherapy of Extragenadal Germinal Cell Neoplasms, Phase II

Start Date 8 Jul 83	Est Comp Date: Unknown
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, M.D., MAJ, MC
Key Words: Germinal cell neoplasm	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 3	
Date of Periodic Review Results	

Objective(s): 1) To determine the effectiveness of alternating combination chemotherapy consisting of VBP (Vinblastine, Bleomycin and Cis-platinum) and EBAP (Bleomycin, Adriamycin, Cis-platinum and VP-16) in patients with metastatic germinal cell neoplasms arising in extragonadal sites.

2) To determine the overall toxicity of the alternating combination of VBP and EBAP.

3) To determine the role of surgical removal of residual disease following this drug combination in partially responding patients.

4) To compare the response rates observed in this study with those reported by other investigators.

Technical Approach: Patients presenting with a histologically confirmed diagnosis of non-resectable extragonadal germ cell tumors are eligible for this study. All patients should have clearly measurable disease, or an abnormally elevated beta HCG and/or alpha fetoprotein. Patients with extragonadal seminomatous and non-seminomatous neoplasms will be eligible for treatment on this study, but will be analyzed separately.

Therapy will follow the schema outlined in the study protocol.

Progress: Twenty-four patients have been entered on this study, and 16 are evaluable. There are 13 complete responses and two partial responses.

Detail Summary Sheet

Date: 18 Sep 85	Proj No: SWOG 8232	Status: Closed
Title: Treatment of Limited Small Cell Lung Cancer with VP-16/Cis-Platinum, Alternating with Vincristine/Adriamycin/Cyclophosphamide and Radiation Therapy vs Concurrent VP-16/Vincristine/Adriamycin...Radiation Therapy, Phase III		
Start Date 14 Jan 83	Est Comp Date:	Unknown
Principal Investigator	Facility	
Glenn M. Mills, M.D., LTC, MC	Brooke Army Medical Center	
Dept/Svc	Associate Investigators:	
Department of Medicine/Oncology		
Key Words:		
Limited small cell lung cancer		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	
Number of Subjects Enrolled During Reporting Period:	1	
Total Number of Subjects Enrolled to Date:	2	
Date of Periodic Review	Results	

Objective(s): 1) To compare the efficacy of alternating non-cross-resistant, multidrug regimens with concurrent combination chemotherapy as remission induction in patients with limited small cell lung carcinoma.

2) To determine the toxicity of these treatment programs.

Technical Approach: All patients must have histologically proven small cell carcinoma of the lung. Prior to treatment, patients should be staged as to the extent of disease. Only patients with limited disease are eligible for this study. They must have evaluable or measurable disease. Patients having a prior surgical procedure are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: Groupwise, there was no evidence of an advantage for the alternating combined arm over repetitive administrations of the same program.

Detail Summary Sheet

Date: 18 Sep 85	Proj No: SWOG 8235	Status: Ongoing
Title: Evaluation of Continuous Infusion Vinblastine in Gastric Carcinoma.		

Start Date 27 Jan 84	Est Comp Date:
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC
Key Words: Gastric carcinoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	1
Total Number of Subjects Enrolled to Date:	2
Date of Periodic Review 9 November 1984	Results Continue

Objective(s): 1) To determine the response rate, response duration, and duration of survival of gastric carcinoma treated with continuous infusion vinblastine.

2) To define the qualitative and quantitative toxicities of continuous infusion vinblastine administered in a Phase II study:

Technical Approach: Eligible patients must have a pathologically verified histologic diagnosis of adenocarcinoma of the stomach with gross unresectable residual disease. Both previously treated and untreated patients will be eligible for this study. Patients must have measurable disease and must not be receiving concomitant radiation therapy, hormonal therapy, or other chemotherapy.

Therapy will follow the schema outlined in the study protocol.

Progress: At this time, only ten patients are response evaluable without responses having been noted.

Detail Summary Sheet

Date: 18 Sep 85 Proj No: SWOG 8237 Status: Ongoing
 Title: Evaluation of Continuous Infusion Vinblastine Sulfate in Pancreatic Adenocarcinoma, Phase II

Start Date 8 Jul 83	Est Comp Date: Unknown
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC
Key Words: Pancreatic adenocarcinoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 3	
Total Number of Subjects Enrolled to Date: 7	
Date of Periodic Review	Results

Objective(s): To determine the clinical response rate of a five-day continuous infusion of vinblastine sulfate in pancreatic adenocarcinoma.

Technical Approach: To be eligible, patients must have a pathologically verified diagnosis of pancreatic adenocarcinoma. They must have objectively measurable or evaluable lesion(s) excluding CNS metastases and a life expectancy of at least eight weeks. Patients must have recovered from the toxicities of previous chemotherapy and/or radiotherapy and have demonstrated progressive disease.

Therapy will follow the schema outlined in the study protocol.

Progress: Twenty-nine patients have been registered on this study. of 18 response evaluable patients, there are two objective partial remissions suggesting some level of anti-tumor activity for vinblastine in this setting.

Detail Summary Sheet

Date: 18 Sep 85 Proj No: SWOG 8239 Status: Closed
 Title: Evaluation of Spirogermanium in CNS Tumors, Phase II.

Start Date 8 Apr 83	Est Comp Date: Unknown
Principal Investigator	Facility
Glenn M. Mills, M.D., MAJ, MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Medicine/Oncology	
Key Words:	
CNS tumors	
Accumulative MEDCASE	Est Accumulative
Cost:	OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 2	
Date of Periodic Review	Results

- Objective(s): 1) To determine the antitumor activity of Spirogermanium in malignant gliomas by evaluation of response-rate.
- 2) To determine the qualitative and quantitative toxicities of Spirogermanium given in a Phase II setting.
- 3) To estimate the duration of survival experienced by these patients.

Technical Approach: Patients must have a histologically-confirmed diagnosis of astrocytomas, Grades III and IV; ependymblastoma; medulloblastoma; or anaplastic oligodendroglioma. They must have failed primary surgical and/or radiation therapies and not be eligible for high higher priority protocols. All should have received adequate prior radiotherapy. All patients must have a measurable lesion by scan and a life expectancy of six weeks or more.

Therapy will follow the schema outlined in the study protocol.

Progress: Twenty-eight patients have been entered with 21 evaluable. Four of the 21 evaluable patients have had measurable shrinkage of tumor with stable or improved neurologic examination for a median duration of 28+ weeks. An additional four patients have had neurologic improvement lasting 5.5 weeks median duration.

Detail Summary Sheet

Date: 18 Sep 85 Proj No: SWOG 8240 Status: Ongoing
 Title: Evaluation of Spirogermanium in the Treatment of Metastatic Malignant Melanoma, Phase II.

Start Date 4 Jan 85	Est Comp Date:
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC
Key Words: Malignant melanoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	0
Total Number of Subjects Enrolled to Date:	0
Date of Periodic Review n/a	Results

Objective(s): 1) To determine the response rate and survival of malignant melanoma treated with spirogermanium.

2) To define the qualitative and quantitative toxicities of spirogermanium administered in a Phase II study.

Technical Approach: All patients must have a pathologically verified histologic diagnosis of advanced malignant melanoma. Spirogermanium is intended as therapy of patients with advanced malignant melanoma with or without prior exposure to, and progression of disease on, protocols of high priority.

Therapy will follow the schema outlined in the study protocol.

Progress: Patient accrual has been very slow.

Detail Summary Sheet

Date: 18 Sep 85 Proj No: SWOG 8241 Status: Closed
 Title: Treatment for Advanced Non-Small Cell Lung Cancer: PVp vs PVpM vs PVe vs PVeMi vs FOMi/CAP, Phase III

Start Date 11 Mar 83	Est Comp Date: Unknown
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators:
Key Words: Non-small cell lung cancer	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 10	
Date of Periodic Review	Results

Objective(s): 1) To directly compare the efficacy and toxicity of Cis-platinum plus VP-16 (PVp) versus Cis-platinum plus Vinblastine (PVe) in patients with advanced (TNM Stage III M1) non-small cell lung cancer (NSCLC).

2) To compare the response rate, response duration, survival and toxicity of Cis-platinum plus VP-16 (PVp) to Cis-platinum plus VP16 plus MGBG (PVpM).

3) To compare the response rate, response duration, survival and toxicity of Cis-platinum plus Vinblastine (PVe) to Cis-platinum plus Vinblastine plus Mitomycin-C (PVeMi).

4) To re-evaluate and compare the activity of FOMi/CAP to PVp, PVpM, PVe and PVeMi using a five-arm, randomized study design.

5) To evaluate differences in response rates among patients with squamous cell carcinoma, adenocarcinoma or large cell undifferentiated carcinoma of the lung.

Technical Approach: All patients with a histologically or cytologically confirmed diagnosis of squamous cell carcinoma, adenocarcinoma or large cell carcinoma of the lung are eligible for this study. The patient's clinical presentation should be compatible with a neoplasm of bronchogenic origin.

Therapy will follow the schema outlined in the study protocol.

Progress: There is no evidence of a difference among the five randomized treatment arms. The response rate is quite low (10-20%) for all treatment arms.

Detail Summary Sheet

Date: 18 Sep 85 Proj No: SWOG 8244 Status: Ongoing
 Title: Clinical Antitumor Activity of Vinblastine Sulfate in Diffuse Mesothelioma, Phase II

Start Date 10 Jun 83	Est Comp Date: Unknown
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC
Key Words: Mesothelioma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review	Results

Objective(s): To determine the clinical response rate of five-day continuous infusion vinblastine sulfate in diffuse malignant mesothelioma.

Technical Approach: To be eligible, patients must hve a pathologically verified diagnosis of mesothelioma. The mesothelioma may arise either in the thorax or abdomen, but must be of the diffuse malignant type (i.e., not locally resectable by surgery). Patients must have objectively measurable or evaluable lesion(s) excluding CNS metastases and a life expectancy of at least eight weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: Seven patients have been entered on this study. There has been one response which occurred in an intra-abdominal mesothelioma and was coded as a partial remission, and lasted 8 weeks by abdominal CT scan.

Detail Summary Sheet

Date: 18 Sep 85 Proj No: SWOG 8263 Status: Ongoing
 Title: Combined Radiation Therapy and Chemotherapy as Adjuvant Treatment for Duke's B2-C Colon Cancer, Phase I-II, Pilot

Start Date 8 Jul 83	Est Comp Date: Unknown
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC
Key Words: Duke's B2-C colon cancer	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 2	
Total Number of Subjects Enrolled to Date: 5	
Date of Periodic Review	Results

Objective(s): To determine the immediate and delayed toxicity of two adjuvant therapy programs for patients with Dukes B2-C colon cancer: intravenous bolus 5-fluorouracil and whole abdominal radiation therapy begun simultaneously four to six weeks postoperatively.

Technical Approach: Patients must have a histologically confirmed diagnosis of Duke's C1 (limited to the serosa with positive nodes) or C2 (extension through the serosa with positive nodes). Patients entering the study postoperatively must have an adequate surgical procedure of the tumors of the cecum and ascending colon, proximal transverse colon, splenic flexure or descending colon, or sigmoid. They must not have had any prior malignancies, inflammatory bowel disease or liver disease. Patients may not have received prior radiation therapy or chemotherapy.

Therapy will follow the schema outlined in the study protocol.

Progress: Twenty-eight patients have been registered on this study. Initial dose of 5-FU was 300 mg/M² days 1-5 and days 29-33. Significant leukopenia and thrombocytopenia was seen with this dose plus total abdominal irradiation requiring interruption of radiotherapy in 13 patients. The 5-FU dose was reduced, and hematologic toxicity has been more tolerable since.

Detail Summary Sheet

Date: 18 Sep 85 Proj No: SWOG 8269 Status: Ongoing
 Title: Concurrent Chemo-Radiotherapy for Limited Small Cell Carcinoma of the Lung, Phase II - Pilot

Start Date 8 Oct 82	Est Comp Date: Unknown
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC
Key Words: Small cell carcinoma of lung	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 2	
Total Number of Subjects Enrolled to Date: 12	
Date of Periodic Review	Results

Objective(s): 1) To explore the response rate with the concurrent use of radiation therapy plus chemotherapy utilizing Cis-platinum VP-16 and Vincristine in limited small cell carcinoma of the lung.

2) To observe the toxicities of this combined modality program.

Technical Approach: Patients with a histologically or cytologically proven diagnosis of small cell carcinoma of the lung will be eligible for this study. All patients must have so-called "limited disease". This is defined as disease confined to one hemithorax, mediastinum, hilar and supraclavicular areas, which could be encompassed within a single radiation therapy port. Patients having had surgical diagnostic or therapeutic techniques are eligible, except if all gross evidence of disease has been removed after surgical resection.

Therapy will follow the schema outlined in the study protocol.

Progress: With 27 patients registered and 16 fully or partially evaluable, 11 have had complete responses and four partial responses. Five patients are now in complete remission beyond a year.

Detail Summary Sheet

Date: 18 Sep 85 Proj No: SWOC 8291 Status: Ongoing
 Title: The Intergroup Adult Adjuvant Soft Tissue Sarcoma Study #1. A Randomized Trial of Adjuvant Doxorubicin (Adriamycin) versus Standard Therapy (A Delay of Chemotherapy Until the Time of Possible Relapse)

Start Date 11 Mar 83	Est Comp Date: Unknown
Principal Investigator	Facility
Glenn M. Mills, M.D., MAJ, MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Medicine/Oncology	Walter H. Harvey, D.O., MAJ, MC
Key Words:	
Soft tissue sarcoma	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review	Results

Objective(s): This prospective randomized study is designed to evaluate the efficacy of adjuvant Adriamycin compared to standard treatment (a delay of chemotherapy until the time of demonstrated relapse) in the management of patients with Stages IIB, IIIA-C and tissue sarcoma in terms of local recurrence rate, disease-free interval, and survival.

Technical Approach: For inclusion in this study, patients must have a histopathologically proven diagnosis of soft tissue sarcoma Stages IIB, IIIA-C, and IVA. The tumor may be either previously untreated or a local recurrence.

Therapy will follow the schema outlined in the study protocol.

Progress: Fifty-five patients have been entered on this study. Thus far, one case of severe leukopenia and one case of severe nausea and vomiting have been reported. No additional reportable data are available.

Detail Summary Sheet

Date: 18 Sep 85 Proj No: SWOG 8292 Status: Ongoing
 Title: Treatment for Brain Metastases, Phase III. Intergruop Study

Start Date 8 Apr 83	Est Comp Date: Unknown
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC
Key Words: Brain metastases	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	4
Total Number of Subjects Enrolled to Date:	5
Date of Periodic Review	Results

Objective(s): 1) To test whether the addition of surgery before radiation therapy is a significant improvement over radiation therapy alone in the treatment of patients with apparent single brain metastases. Endpoints studied will be:

One year survival rates and median survival times.

Local control rates of brain metastases one month and six months after treatment.

Improvement of neurological deficit as measured by the percentage of patients with improved neurological function.

2) To evaluate patient refusal with respect to the surgical component.

Technical Approach: All patients having histologically confirmed cancer with evidence of a potentially resectable single intracranial mass lesion as documented by a contrast-enhanced CAT scan are eligible. Only patients with apparently resectable cerebellar or cerebral cortex lesions will be eligible. Patients with bronchogenic carcinoma should have control of the primary tumor and no other metastases prior to admission on this study.

Progress: Patient accrual has improved significantly. No reportable data are available.

Detail Summary Sheet

Date: 18 Sep 85 Proj No: SWOG 8293 Status: Ongoing
 Title: Intergroup Phase III Protocol for the Management of Locally or Regionally Recurrent but Surgically Resectable Breast Cancer.

Start Date 25 May 84	Est Comp Date: Unknown
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC
Key Words: Breast cancer	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 November 1984 Results Continue	

Objective(s): 1) To better define the relative roles of systemic and local treatments in the care of resectable locally or regionally recurrent cancer of the breast in patients who have no evidence of disease after resection.

2) To assess the effects of chemotherapy, radiation therapy, singly or in combination, administered immediately after surgical resection on control, disease-free interval and pattern of re-recurrence.

3) To determine the effects of the administration of systemic chemotherapy or radiation therapy which has been delayed until local, regional, re-recurrence upon local and regional control, disease-free survival, patterns of relapse, and survival.

Technical Approach: To be eligible, patients must have undergone a surgical resection with tumor-free margins leaving the patient clinically free of disease less than 6 weeks prior to entry into the study. Patients must have histologically proven technically resectable locally or regionally recurrent breast cancer, the primary of which was initially treated by surgery without postoperative irradiation.

Therapy will follow the schema outlined in the study protocol.

Progress: No reportable data are available at this time.

Detail Summary Sheet

Date: 18 Sep 85	Proj No: SWOG 8294	Status: Ongoing
Title: Evaluation of Adjuvant Therapy and Biological Parameters in Node Negative Operable Female Breast Cancer (ECOG EST-1180), Intergroup, Study (Observation Only) (Patients Randomized to CMFP Chemotherapy)		
Start Date 11 Mar 83	Est Comp Date:	Unknown
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center	
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC	
Key Words: Breast cancer		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	
Number of Subjects Enrolled During Reporting Period: 14		
Total Number of Subjects Enrolled to Date: 26		
Date of Periodic Review Results		

Objective(s): 1) To assess the impact of short-term intensive chemotherapy with CMFP to prevent disease recurrence and prolong survival in N- patients with any size ER- tumor and N- patients with ER+ tumors whose pathological size is greater than or equal to 3 cm.

2) To assess the impact of surgical procedures, ER status, menopausal status and tumor size.

3) To develop guidelines referable to histopathological features of N- tumors which are reproducible and assess their prognostic impact for disease-free survival and survival.

4) To assess the value to CEA in predicting recurrence and survival rates.

5) To assess the natural history of a subgroup with N-, ER+ small tumors.

Technical Approach: All female patients having had at least a total mastectomy with an axillary dissection or total mastectomy with low axillary dissection for potentially curable breast carcinoma as defined in this protocol and having no histopathological evidence of axillary node involvement will be considered for inclusion in this study.

Therapy will follow the schema outlined in the study protocol.

Progress: No reportable data are available at this time.

etail Summary Sheet

Date: 18 Sep 85 Proj No: SWOG 8300 Status: Ongoing
 Title: Treatment of Limited Non-Small Cell Lung Cancer: Radiation vs Raidation plus Chemotherapy (FOMi/CAP), Phase III.

Start Date 26 Oct 84	Est Comp Date:
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC
Key Words: Non-small cell lung cancer	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 4	
Total Number of Subjects Enrolled to Date: 4	
Date of Periodic Review n/a	Results

Objective(s): 1) To compare combination chemotherapy plus radiotherapy to radiotherapy alone for patients with limited, non-small cell lung cancer (NSCLC) in a randomized study with stratification for known important prognostic factors with regard to response rate, response duration and survival duration.

2) To determine the toxicity of radiotherapy plus FOMi/CAP relative to radiotherapy alone for patients with limited NSCLC.

3) To evaluate the responsiveness of small tumor burdens to FOMi/CAP (i.e., less than metastatic disease).

4) T determine the pattern of relapsing disease in each treatment arm and in subgroups of patients determined by histology and response to FOMi/CAP.

5) To determine if prophylactic brain irradiation will decrease the chances for brain metastases and influence toxicity or survival.

Technical Approach: All patients must have a histologic or cytologic diagnosis of non-small cell carcinoma of the lung. Patients must have limited disease. Disease must be confined to a single hemithorax, and/or ipsilateral hilar lymph nodes, and/or the mediastinum, and/or the ipsilateral supraclavicular lympho nodes. In addition, the patient's disease must be encompassable in a single radiation port.

Therapy will follow the schema outlined in the study protocol.

Progress: No reportable data are available.

Detail Summary Sheet

Date: 9 Apr 85 Proj No: SWOG 8302 Status: Completed
 Title: Phase II Study of Doxorubicin, Mitomycin-C and 5-Fluorouracil in the
 Treatment of Metastatic Adenocarcinoma of the Prostate.

Start Date 4 Nov 83	Est Comp Date:
Principal Investigator James F. Boyd, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Glenn M. Mills, M.D., MAJ, MC
Key Words: Adenocarcinoma Prostate	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 2	
Date of Periodic Review	Results

Objective(s): To test the effectiveness and toxicity of DMF (Doxorubicin, Mitomycin-C, and 5-Fluorouracil) in the treatment of Stage D₂ adenocarcinoma of the prostate.

Technical Approach: Patients with histologically proven, metastatic adenocarcinoma of the prostate with measurable disease are eligible. Patients with blastic bone lesions on x-ray as a sole manifestation of metastases are not eligible. However, patients with bone metastases only who have positive bone scans will be eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: Groupwide, 62 patients have been entered on this study with 23 evaluable. One complete remission, eight partial responses and six patients with stable disease have been documented.

Detail Summary Sheet

Date: 18 Sep 85 Proj No: SWOG 8303 Status: Closed
 Title: Evaluation of 2'Deoxycoformycin in Refractory Multiple Myeloma, Phase II

Start Date 8 Jul 83	Est Comp Date: Unknown
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC
Key Words: Multiple myeloma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review	Results

Objective(s): 1) To determine the response rate and response duration of refractory multiple myeloma treated with low dose 2'Deoxycoformycin used in a single dose, every two week schedule.

2) To define the qualitative and quantitative toxicities of 2'Deoxycoformycin administered in a Phase II study.

Technical Approach: 2'Deoxycoformycin is intended for therapy of patients with multiple myeloma who have had prior exposure to and progression of disease on protocols of higher priority. All patients must have a pathologically verified histologic diagnosis of multiple myeloma. Only symptomatic patients or those with demonstrated progressive disease are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: Fifteen patients are evaluable. There has been some renal toxicity in a few patients but no other major toxicity. No responses have been observed.

Detail Summary Sheet

Date: 9 Apr 85 Proj No: SWOG 8304 Status: Completed
 Title: Evaluation of L-Alanosine in Metastatic Carcinoma of the Breast

Start Date 8 Jul 83	Est Comp Date: Unknown
Principal Investigator James F. Boyd, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Glenn M. Mills, M.D., MAJ, MC
Key Words: Metastatic carcinoma of breast	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	0
Total Number of Subjects Enrolled to Date:	3
Date of Periodic Review	Results

Objective(s): 1) To determine the antitumor activity as determined by response rate and duration of response of L-Alanosine used on a three day, every three week schedule in patients with metastatic carcinoma of the breast who have failed on standard therapy.

2) To determine the nature and degree of toxicity of L-Alanosine.

Technical Approach: All patients with metastatic carcinoma of the breast resistant to standard chemotherapeutic agents are eligible. Patients must have measurable or evaluable disease and a life expectancy of at least nine weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: Thirty-five patients were entered onto this Phase II trial. Toxicity was mild. There were apparently no significant responses.

Detail Summary Sheet

Date: 27 Mar 85 Proj No: SWOG 8305 Status: Closed
 Title: Chemotherapy of Metastatic Colorectal Carcinoma with 5-FU and Folinic Acid, Phase II

Start Date 8 Jul 83	Est Comp Date: Unknown
Principal Investigator James F. Boyd, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Glenn M. Mills, M.D., MAJ, MC
Key Words: Colorectal carcinoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 6	
Date of Periodic Review	Results

Objective(s): 1) To determine the toxicity of 5-fluorouracil (5-FU) and folinic acid (CF) therapy in patients with metastatic colorectal carcinoma.

2) To determine the response-rate in previously untreated patients receiving 5-FU and folinic acid.

Technical Approach: Patients must have clinically measurable disease to qualify for this study. They must have biopsy-proven adenocarcinoma arising from the colon or rectum. Obstructive lesions in the colon and rectum must have been bypassed or adequately maintained by decompression measures.

Therapy will follow the schema outlined in the study protocol.

Progress: One hundred twenty-eight patients have been randomly assigned to the two treatment arms. Of the 30 fully evaluable patients treated by constant infusion 5-FU, 7 or 23% had an objective partial response. In the 31 fully evaluable patients treated by 5-FU bolus there were 8 responses or 25%. Survival for the two arms is essentially identical.

Detail Summary Sheet

Date: 18 Sep 85 Proj No: SWOG 8308 Status: Ongoing
 Title: Combination of Cis-Platinum and Dichloromethotrexate in Patients with Advanced Bladder Cancer, Phase II.

Start Date 27 Jan 84	Est Comp Date:
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC
Key Words: Bladder cancer	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 2	
Total Number of Subjects Enrolled to Date: 2	
Date of Periodic Review 9 November 1984	Results Continue

Objective(s): 1) To obtain data regarding the activity and toxicity of combination cis-platinum and dichloromethotrexate in patients with objectively measurable metastatic transitional cell carcinoma of the bladder who have good renal function and who have not previously received chemotherapy.

2) To investigate the single agent activity and toxicity of dichloromethotrexate in previously untreated patients with impaired renal function.

Technical Approach: Eligible patients must have a histologically confirmed diagnosis of metastatic transitional cell carcinoma of the urothelium. Only patients without prior systemic chemotherapy are eligible for this study. Patients with prior radiotherapy are eligible if the disease has progressed, if at least six weeks have elapsed since completion of the radiotherapy (non-cranial) and if measurable sites of disease exist outside of the previous radiation field.

Therapy will follow the schema outlined in the study protocol.

Progress: Twenty-five patients have been entered on this study, 17 on the cis-platinum plus dichloromethotrexate and 8 on the dichloromethotrexate alone arm. In the combination arm, there has been one complete response and three partial responses in eight patients. There have been no responses on the dichloromethotrexate alone arm.

Detail Summary Sheet

Date: 18 Sep 85 Proj No: SWOG 8310 Status: Ongoing
 Title: Evaluation of Aziridinybenzoquinone (AZQ) in Refractory and Relapsing Myeloma, Phase II.

Start Date 26 Apr 85	Est Comp Date:
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC
Key Words: Myeloma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	0
Total Number of Subjects Enrolled to Date:	0
Date of Periodic Review	Results

Objective(s): 1) To determine the antitumor activity of Aziridinybenzoquinone (AZQ) in patients with refractory and relapsing multiple myeloma by determination of the response rate and the remission duration.

2) To define the qualitative and quantitative toxicities of AZQ administered in a phase II study.

Technical Approach: All patients must have a pathologically verified histologic diagnosis of multiple myeloma. AZQ is intended for therapy of patients with multiple myeloma who have had prior exposure to, and progression of disease on, protocols of higher priority.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. No reportable data are available.

etail Summary Sheet

Date: 18 Sep 85	Proj No: SWOG 8311	Status: Closed
Title: Combination Chemotherapy with Cis-Platinum, Vinblastine, and Methylglyoxal Bis (Guanylhydrazone) (MGBG) in Epidermoid Carcinoma of the Esophagus		
Start Date 9 Sep 83	Est Comp Date:	Unknown
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center	
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC	
Key Words: Epidermoid carcinoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	
Number of Subjects Enrolled During Reporting Period: 0		
Total Number of Subjects Enrolled to Date: 1		
Date of Periodic Review	Results	

Objective(s): 1) To define the response rate and duration, as well as survival duration, in patients with advanced epidermoid carcinoma of the esophagus when treated with Cis-platinum, Vinblastine and MGBG.

2) To determine the toxicity of this regimen in the treatment of epidermoid carcinoma of the esophagus.

Technical Approach: All patients must have measurable disease and must have histologically or cytologically confirmed diagnosis of epidermoid carcinoma of the esophagus.

Therapy will follow the schema outlined in the study protocol.

Progress: Currently there are 39 patients registered on this study. Of 18 evaluable patients, only four have responded to date. This study is closed to new patient entries.

etail Summary Sheet

Date: 18 Sep 85 Proj No: SWOG 8312 Status: Ongoing
 Title: Megestrol Acetate and Aminoglutethimide/Hydrocortisone in Sequence or in Combination as Second-Line Endocrine Therapy of Estrogen Receptor Positive Metastatic Breast Cancer, Phase III

Start Date 31 Aug 84	Est Comp Date:
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC
Key Words: Breast cancer	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 November 1984 Results Continue	

Objective(s): 1) To determine whether combination hormonal therapy with Aminoglutethimide and Hydrocortisone (AH) plus Megestrol Acetate (M), agents thought to have different mechanisms of action, offers an improved response rate with prolonged response duration and increased patient survival over the sequential use of each agent in Estrogen Receptor (ER) positive patients who have progressed after responding to primary hormonal treatment with Tamoxifen.

2) To assess the relative toxicities of Megestrol Acetate and medical adrenalectomy.

3) To assess the value of progesterone receptor (PgR) in predicting subsequent responses to a variety of hormonal therapies.

Technical Approach: Postmenopausal female patients with progressive, measurable metastatic breast carcinoma are eligible. Patients must have received an adequate trial of tamoxifen therapy and achieved at least a partial response in all areas of measurable disease.

Therapy will follow the schema outlined in the study protocol.

Progress: Patient accrual has been extremely poor. There have been no significant toxicities or other problems.

Detail Summary Sheet

Date: 18 Sep 85 Proj No: SWOG 8313 Status: Ongoing
 Title: Multiple Drug Adjuvant Chemotherapy for Patients with ER Negative Stage II Carcinoma of Breast, Phase III.

Start Date 31 Aug 84	Est Comp Date:
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC
Key Words: Breast carcinoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 8 November 1984 Results Continue	

Objective(s): 1) To compare through a randomized prospective study, the recurrence rates and disease-free intervals (DFI) for postoperative axillary node positive estrogen receptor negative (ER-) breast cancer patients given adjuvant therapy with either short term intense chemotherapy (FAC-M) or one year standard chemotherapy (CMFVP).

2) To compare the effect of these two adjuvant therapies on survival.

3) To compare the relative toxicity of the two therapies.

Technical Approach: All patients must have histologically proven breast carcinoma with metastases to one or more axillary nodes to be eligible. Only patients with ER- breast carcinoma are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: It is too early to report any meaningful information.

Detail Summary Sheet

Date: 18 Sep 85 Proj No: SWOG 8316 Status: Ongoing
 Title: Evaluation of Fludarabine Phosphate (NSC-312887) in Renal Cell Carcinoma, Phase II.

Start Date 22 Aug 84	Est Comp Date:
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC
Key Words: Fludarabine phosphate Renal cell carcinoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 8 November 1984	Results Continue

Objective(s): 1) To determine the response rate and remission duration of renal cell carcinoma when treated with Fludarabine Phosphate.

2) To define the qualitative and quantitative toxicities of Fludarabine Phosphate administered in a Phase II study.

Technical Approach: Eligible patients must have a histologically confirmed diagnosis of renal cell carcinoma and no be eligible for Southwest Oncology Group protocols of higher priority. Only patients who have received no prior chemotherapy regimens will be eligible. Patients must have clearly measurable disease and a life expectancy of at least six weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: There are 36 patients registered on this study with 22 evaluable. There has been one possible response.

Detail Summary Sheet

Date: 19 Sep 85 Proj No: SWC 8318 Status: Ongoing
 Title: Evaluation of Fludarabine Phosphate in Hepatoma, Phase II.

Start Date 26 Oct 84	Est Comp Date:
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC
Key Words: Hepatoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	1
Total Number of Subjects Enrolled to Date:	1
Date of Periodic Review n/a	Results

Objective(s): 1) To determine the response rate and response duration of hepatomas treated with Fludarabine Phosphate (5-Fluoro-ara-AMP).

2) To define the qualitative and quantitative toxicities of Fludarabine Phosphate in a Phase II study.

Technical Approach: To be eligible for this study, patients must have a pathologically verified histologic diagnosis of hepatoma, must not have received any previous chemotherapeutic regimens, and must have measurable disease.

Therapy will follow the schema outlined in the study protocol.

Progress: Groupwide, this study has accrued 11 patients. No reportable data are available at this time.

etail Summary Sheet

Date: 18 Sep 85 Proj No: SWOG 8319 Status: Ongoing
 Title: Evaluation of Fludarabine Phosphate in Ovarian Cancer, Phase II.

Start Date 31 Aug 84	Est Comp Date:
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC
Key Words: Cancer, ovarian	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 November 1984 Results Continue	

Objective(s): 1) To determine the antitumor activity of Fludarabine Phosphate (2-Fluoro-ara-AMP) in patients with metastatic or recurrent epithelial carcinomas of the ovary who have failed on higher priority treatment protocols.

2) To determine the nature and degree of toxicity of Fludarabine Phosphate.

Technical Approach: All patients not eligible for higher priority studies with histologically proven incurable advanced metastatic or recurrent epithelial carcinoma of the ovary are eligible. All patients must have failed primary chemotherapy regimens and have a life expectancy of at least six weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: Too few patients have been entered on this study to draw any conclusions.

Detail Summary Sheet

Date: 18 Sep 85 Proj No: SWOG 8320 Status: Ongoing
 Title: Evaluaton of Fludarabine Phosphate in Endometrial Cancer, Phase II.

Start Date 31 Aug 84	Est Comp Date:
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC
Key Words: Cancer, endometrial	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 8 November 1984 Results Continue	

Objective(s): 1) To determine the antitumor ctivity of Fludarabine Phosphate in patients with metastatic or recurrent epithelial carcinomas of the endometrium who have failed on higher priority treatment protocols.

2) To determine the nature and toxicity of Fludarabine Phosphate.

Technical Approach: All patients not eligible for higher priority Southwest Oncology Group studies with histologically proven incurable advanced metastatic or recurrent epithelial carcinoma of the endometrium are eligible. Patients must have a life expectancy of six weeks and clearly measurable disease.

Therapy will follow the schema outlined in the study protocol.

Progress: Too few patients have been entered into this study to draw any conclusions.

Detail Summary Sheet

Date: 19 Sep 85	Proj No: SWOG 8321	Status: Ongoing
Title: Evaluation of Carboplatin vs Cisplatinum + Infusion 5-Fluorouracil + Allopurinol in the Treatment of Metastatic or Recurrent Squamous Carcinoma of the Uterine Cervix, Phase II.		

Start Date 26 Apr 85	Est Comp Date:
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC
Key Words: Carcinoma, uterine cervix	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	0
Total Number of Subjects Enrolled to Date:	0
Date of Periodic Review n/a	Results

Objective(s): 1) To carry out a randomized phase II trial of two treatment regimens, carboplatin and cisplatin/continuous infusion 5-FU + allopurinol in patients with metastatic or recurrent squamous carcinoma of the cervix who have failed treatment protocols of higher priority.

2) To determine and compare the nature and degrees of toxicity of each of these treatment regimens.

Technical Approach: All patients with histologically proven metastatic or recurrent squamous carcinoma of the uterine cervix are potential candidates for this study. Patients must have a life expectancy of at least 6 weeks, a performance status of 0-2, and measurable disease.

Therapy will follow the schema outlined in the study protocol.

Progress: This is anew study. No reportable data are available.

Detail Summary Sheet

Date: 18 Sep 85 Proj No: SWOG 8322 Status: Ongoing
 Title: Evaluation of Fludarabine Phosphate in Advanced Sarcomas, Phase II.

Start Date 31 Aug 84	Est Comp Date:
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC
Key Words: Sarcoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 8 November 1984 Results Continue	

Objective(s): 1) To determine the response rate and response duration of advanced sarcomas treated with fludarabine phosphate.

2) To define the qualitative and quantitative toxicities of fludarabine phosphate administered in a Phase II study.

Technical Approach: To be eligible, all patients must have a pathologically verified histologic diagnosis of sarcoma. Patients must have measurable disease and must not be receiving concomitant radiation, hormonal or chemotherapy.

Therapy will follow the schema outlined in the study protocol.

Progress: No responses and only mild myelosuppression have been noted in the six patients accrued in this study.

Detail Summary Sheet

Date: 18 Sep 85 Proj No: SWOG 8323 Status: Ongoing
 Title: Evaluation of Fludarabine Phosphate in Advanced Mycosis Fungoides,
 Phase II.

Start Date 28 Sep 84	Est Comp Date:
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC
Key Words: Mycosis fungoides	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 November 1984 Results Continue	

Objective(s): 1) To determine the response-rate and remission duration of treatment with low dose fludarabine phosphate used on an every three-week schedule in advanced mycosis fungoides.

2) To define the qualitative and quantitative toxicities of the drug when administered in a Phase II study.

Technical Approach: Patients must have advanced mycosis fungoides with at least extensive plaque disease, or skin nodules, gross skin tumor, lymph node involvement or extranodal involvement. All patients must have measurable disease clearly documented prior to initiation of therapy.

Therapy will follow the schema outlined in the study protocol.

Progress: Nine patients have been registered. It is too early to report any meaningful data.

Detail Summary Sheet

Date: 18 Sep 85 Proj No: SWOG 8325 Status: Ongoing
 Title: Combination Chemotherapy with Mitotane (O,P'-DDD) and Cis-Platinum
 in Metastatic Adrenal Carcinoma, Phase II.

Start Date 2 May 84	Est Comp Date:
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC
Key Words: Adrenal carcinoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 9 November 1984	Results Continue

- Objective(s): 1) To study the responsiveness of adrenocortical carcinoma to combination chemotherapy consisting of Cis-Platinum (DDP) and Mitotane (O,P'-DDD).
- 2) To study the prognostic features of patients with metastatic and/or unresectable adrenal carcinoma receiving chemotherapy.
- 3) To document the toxicity of chemotherapy in this group of patients.

Technical Approach: Patients with metastatic or residual adrenocortical carcinoma in whom further surgical removal of disease is not possible will be eligible. Prior treatment with O,P'-DDD or radiotherapy is allowed. Prior chemotherapy with agents other than cis-platinum is also acceptable.

Progress: Four patients have been accrued to this study; it is too early for an evaluation.

Detail Summary Sheet

Date: 19 Sep 85 Proj No: SWOG 8326/27 Status: Ongoing
 Title: Evaluation of Combination Chemotherapy Using High Dose Ara-C in Adult Acute Leukemia and Chronic Granulocytic Leukemia in Blastic Crisis, Phase III.

Start Date 30 Aug 85	Est Comp Date:
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC
Key Words: Leukemia, adult acute Leukemia, chronic granulocytic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	0
Total Number of Subjects Enrolled to Date:	0
Date of Periodic Review n/a	Results

Objective(s): 1) To compare the effectiveness of three different drug combinations using high dose Ara-C alone or high dose Ara-C in combination with m-AMSA or Mitoxantrone for remission induction in relapsed adult leukemias including both acute non-lymphocytic leukemia, chronic granulocytic during accelerated or blastic phase, as well as untreated secondary acute leukemias.

2) To monitor the side effects of the above combination chemotherapy schedules.

Technical Approach: All patients with the following types of leukemia in relapse (including CNS involvement) are eligible: 1) Acute non-lymphocytic leukemia including newly diagnosed secondary leukemia, and ANLL with failure of induction from standard chemotherapy; 2) Chronic granulocytic leukemia during accelerated phase or blastic phase.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. No reportable data are available.

Detail Summary Sheet

Date: 18 Sep 85 Proj No: SWOG 8328 Status: Ongoing
 Title: Evaluation of Fludarabine Phosphate in Cervical Cancer, Phase II.

Start Date 31 Aug 84	Est Comp Date:
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC
Key Words: Cancer, cervical	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 9 November 1984 Results Continue	

Objective(s): 1) To determine the antitumor activity of Fludarabine Phosphate in patients with metastatic or recurrent epithelial carcinomas of the cervix who have failed on higher priority treatment protocols.

2) To determine the nature and degree of toxicity of Fludarabine Phosphate.

Technical Approach: All patients not eligible for higher priority Southwest Oncology Group studies with histologically proven incurable advanced metastatic or recurrent epithelial carcinoma of the cervix are eligible. Patients must have measurable disease and a life expectancy of six weeks.

Progress: Groupwide, five patients have been entered into this study. The drug has been well tolerated. Response data are pending.

Detail Summary Sheet

Date: 27 Mar 85 Proj No: SWOG 8360 Status: Closed
 Title: Use of the Surgically Implanted "Infusaid" Pump for Ambulatory
 Outpatient Hepatic Arterial Chemotherapy for Patients with Colon Cancer
 Metastatic to the Liver, Phase II - Pilot

Start Date 13 May 83	Est Comp Date: Unknown
Principal Investigator James F. Boyd, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Glenn M. Mills, M.D., MAJ, MC
Key Words: Infusaid pump Colon cancer Hepatic arterial chemotherapy	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 6	
Date of Periodic Review Results	

Objective(s): 1) To determine the response rate, disease-free interval and survival in patients with colon carcinoma metastatic to the liver treated using the "Infusaid" pump with continuous intrahepatic arterial infusions of 5-FUDR and monthly cis-platinum injections via the side port.

2) To determine the feasibility of utilizing the "Infusaid" pump to deliver intraarterial chemotherapy in a cooperative group setting.

Technical Approach: To be eligible for inclusion on this study, patients must have a biopsy-proven colorectal cancer metastatic to the liver as the primary factor determining their survival and quality of life. Patients will be stratified for hepatic-only versus extra-hepatic disease at the time of registration. Patients must have an estimated survival of greater than 60 days.

Therapy will follow the schema outlined in the study protocol.

Progress: Twenty-one of 43 evaluable patients or 49% achieved a response (5 CR + 16 PR). The protocol is closed to case entry.

Detail Summary Sheet

Date: 10 Apr 85 Proj No: SWOG 8364 Status: Ongoing
 Title: Immediate Postoperative Adjuvant Chemotherapy in Patients with Operable Breast Cancer, Phase II-Pilot.

Start Date 10 Feb 84	Est Comp Date:
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC
Key Words: Breast cancer	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 3	
Date of Periodic Review 9 November 1984	Results Continue

Objective(s): To assess the toxicity of immediate chemotherapy with Cyclophosphamide, Methotrexate, 5-Fluorouracil, Vincristine and Prednisone beginning at the time of surgery in patients with Stage II carcinoma of the breast.

Technical Approach: All female patients with biopsy proven disease of breast cancer which appears to be operable and patients with clinical T₁₋₃N₀₋₁ are eligible. Patients may receive radical, modified radical, total mastectomy, or lumpectomy and axillary node dissection or segmental mastectomy plus axillary node dissection. Patients receiving mastectomy other than segmental or lumpectomy may electively receive radiation therapy at the discretion of the treating physician.

Therapy will follow the schema outlined in the study protocol.

Progress: Groupwide, twenty-two patients have been registered on this study. Observation to date reveals a marked increase in skin toxicity when methotrexate is given simultaneously with radiotherapy. Methotrexate has now been removed from this treatment regimen during radiotherapy.

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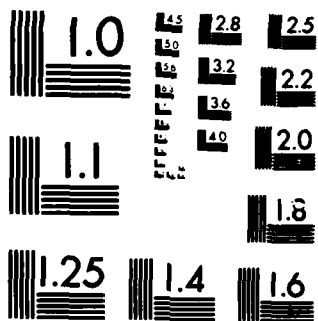
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etail Summary Sheet

Date: 20 Sep 85 Proj No: SWOG 8369 Status: Ongoing
 Title: Combination Chemotherapy with Mitoxantrone, Cis-Platinum and MGBG for Refractory Lymphoma, Phase II.

Start Date 20 Aug 85	Est Comp Date:
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC
Key Words: Lymphoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	0
Total Number of Subjects Enrolled to Date:	0
Date of Periodic Review	Results

Objective(s): 1) To determine if the combination of Mitoxantrone, Cis-Platinum and Methyl-Glyoxal Bis-Guanylhydrazone (MGBG) has reasonable activity (response rate >30%) in patients with refractory unfavorable histology non-Hodgkin's lymphoma. Response duration will also be assessed.

2) To determine the toxicities of this combination of drugs.

Technical Approach: Patients must have histologically confirmed unfavorable histology non-Hodgkin's lymphomas refractory to standard chemotherapy. Patients must have received no more than one prior chemotherapy regimen and must have measurable disease.

Therapy will follow the schema outlined in the study protocol.

Progress: Groupwide, five patients have been registered. The regimen appears to be reasonably well tolerated and there is at least one complete remission to date.

Detail Summary Sheet

Date: 20 Sep 85 Proj No: SWOG 8378 Status: Ongoing
 Title: Evaluation of Fludarabine Phosphate in Chronic Lymphocytic Leukemia, Phase I-II.

Start Date 2 Aug 85	Est Comp Date:
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC
Key Words: Leukemia, Chronic lymphocytic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review	Results

Objective(s): 1) To determine the response rate and remission duration of relapsing or refractory chronic lymphocytic leukemia treated with Fludarabine Phosphate used in a daily times five, every four week schedule.

2) To define the qualitative and quantitative toxicities of Fludarabine Phosphate in a Phase II study in this population.

Technical Approach: All patients must have a diagnosis of relapsing or refractory adult chronic lymphocytic leukemia which requires a peripheral count of greater than 15,000 lymphocytes/ l with >40% lymphocytes in the marrow. To be eligible for this protocol, patients with CLL must have bone marrow failure or preogressive disease no responding to a prednisone-containing combination.

Therapy will follow the schema outlined in the study protocol.

Progress: Of seven patients evaluable, four have shown evidence of a partial remission.

Detail Summary Sheet

Date: 18 Sep 85 Proj No: SWOG 8386 Status: Closed
 Title: Evaluation of Fludarabine Phosphate in Colorectal Carcinoma, Phase II.

Start Date 2 May 84	Est Comp Date:
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators:
Key Words: Colorectal carcinoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 2	
Total Number of Subjects Enrolled to Date: 2	
Date of Periodic Review	Results

Objective(s): 1) To determine the antitumor activity of Fludarabine Phosphate in patients with colorectal by determination of the response-rate and remission duration.

2) To further define the qualitative and quantitative toxicities of this drug in a Phase II study.

Technical Approach: Patients must have clinically measurable recurrent or disseminated disease to qualify for the study. Patients must have a life expectancy of at least ten weeks. Patients must not have received any prior chemotherapy and must not be receiving concomitant radiation therapy or hormonal therapy while on this study.

Therapy will follow the schema outlined in the study protocol.

Progress: There have been 22 patients entered into this study. Of the 5 evaluable patients, 2 patients have no response and 3 have increasing disease. This study has been closed to new entries.

Detail Summary Sheet

Date: 18 Sep 85 Proj No: SWOG 8391 Status: Ongoing
 Title: The Intergroup Adult Adjuvant Soft Tissue Sarcoma Study Protocol #2: A
 Randomized Trial of Adjuvant Doxorubicin (Adriamycin) vs Standard Therapy.

Start Date 10 Jun 83	Est Comp Date: Unknown
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, M.D., MAJ, MC
Key Words: Soft tissue sarcoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review	Results

Objective(s): 1) To evaluate the effectiveness of adjuvant chemotherapy in improving the local control rate in inoperable, unresectable or incompletely resected soft tissue sarcomas treated with radiotherapy.

2) To determine the effect of adjuvant chemotherapy on the incidence of metastases, disease-free interval and survival.

3) To evaluate tolerance (with emphasis on local tissue tolerance in the irradiated area) to combined chemotherapy and radiation therapy.

Technical Approach: Eligible patients must have histopathologically proven diagnosis of soft tissue sarcoma. Patients with localized sarcomas, newly diagnosed or recurrent after previous surgery who are not candidates for curative surgical resection, or who have residual tumor following an incomplete surgical resection will be candidates for the study.

Therapy will follow the schema outlined in the study protocol.

Progress: No reportable data are available t this time.

Detail Summary Sheet

Date: 18 Sep 85	Proj No: SWOG 8393	Status: Ongoing
Title: MEL 82 323, National Intergroup Protocol for Intermediate Thickness Melanoma 1.0 to 4.0 MM - Evaluation of Optimal Surgical Margins (2 vs 4 cm) Around the Primary Melanoma and Evaluation of Elective Regional Lymph Node Dissection.		
Start Date 13 Jan 84	Est Comp Date:	
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center	
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC	
Key Words: Melanoma		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	
Number of Subjects Enrolled During Reporting Period:	0	
Total Number of Subjects Enrolled to Date:	0	
Date of Periodic Review 8 November 1984	Results	Continue

- Objective(s): 1) To determine the safest excision margins around the primary melanoma.
- 2) To evaluate the management of the regional lymph nodes (immediate vs delayed lymphadenectomy).
- 3) To evaluate the relative prognostic value of various histopathological parameters of melanoma.

Technical Approach: Patients with primary malignant melanomas of the skin measuring 1.0 to 4.0 mm thick with clinical stage I disease will be eligible for this trial. Patient must have a life expectancy of at least ten years from the time of diagnosis to permit long-term evaluation and follow-up.

Therapy will follow the schema outlined in the study protocol.

Progress: Accrual for this study has been slow. No reportable data are available.

Detail Summary Sheet

Date: 20 Sep 85 Proj No: SWOG 8400/05 Status: Ongoing
 Title: Evaluation of AT-125 and Fludarabine Phosphate in Central Nervous System Tumors, Phase II.

Start Date 26 Apr 85	Est Comp Date:
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC
Key Words: Central Nervous System Tumors	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	1
Total Number of Subjects Enrolled to Date:	1
Date of Periodic Review n/a	Results

Objective(s): 1) To determine the efficacy of AT-125 (Acivicin) and Fludarabine Phosphate given on a daly times five schedule for the treatment of malignant gliomas by determination of response rate, duration and survival.

2) To determine the qualitative and quantitative toxicities of AT-125 and Fludarabine Phosphate in this randomized Phase II setting.

3) To determine the salvage response rate of AT-125 or Fludarabine Phosphate in malignant gliomas failing one of these two agents.

Technical Approach: All patients who have a histologically confirmed diagnosis of malignant glioma will be eligible. Patients must have recurrent or residual measurable disease. All patients should have received adequate prior radiation therapy.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. No reportable data are available.

Detail Summary Sheet

Date: 20 Sep 85 Proj No: SWOG 8402 Status: Ongoing
 Title: Evaluation of Esorubicin in Ovarian Cancer, Phase II.

Start Date 26 Apr 85	Est Comp Date:
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC
Key Words: Ovarian cancer	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review n/a	Results

Objective(s): 1) To determine the anti-tumor activity of Esorubicin (4'deoxydoxorubicin) in patients with metastatic or recurrent epithelial carcinomas of the ovary who have failed on higher priority treatment protocols.

2) To define the qualitative and quantitative toxicities of Esorubicin administered in a Phase II study.

Technical Approach: All patients must have a histopathologically verified diagnosis of incurable advanced metastatic or recurrent epithelial carcinoma of the ovary and must have failed primary therapy. Patients must have a life expectancy of at least 8 weeks and a performance status 0-2.

Therapy will follow the schema outlined in the study protocol.

Progress: Too few patients have been entered to allow evaluation.

Detail Summary Sheet

Date: 20 Sep 85 Proj No: SWOG 8403 Status: Ongoing
 Title: Evaluation of Fludarabine Phosphate in Squamous Cell Carcinoma of the Head and Neck Region, Phase II

Start Date 4 Dec 84	Est Comp Date:
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC
Key Words: Squamous cell carcinoma of head and neck	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review n/a	Results

Objective(s): 1) To determine the response rate and remission duration in patients with advanced squamous cell carcinoma of the head and neck treated with Fludarabine Phosphate.

2) To define further the qualitative and quantitative toxicities of Fludarabine Phosphate.

Technical Approach: Patients must have a verified histologic diagnosis of squamous cell carcinoma of the head and neck region. All patients must have measurable disease.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. No reportable data are available at this time.

Detail Summary Sheet

Date: 20 Sep 85	Proj No: SWOG 8406	Status: Ongoing
Title: Evaluation of Esorubicin (4'Deoxydoxorubicin) in Malignant Lymphoma, Phase II.		

Start Date 4 Dec 84	Est Comp Date:
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC
Key Words: Lymphoma, malignant	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review n/a/	Results

Objective(s): 1) To determine the response rate and response duration of malignant lymphoma treated with Esorubicin.

2) To define the qualitative and quantitative toxicities of Esorubicin administered in a Phase II study.

Technical Approach: All patients must have a pathologically verified histologic diagnosis of malignant lymphoma. Patients must have a life expectancy of more than 8 weeks and must have evaluable disease.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. No reportable data are available.

Detail Summary Sheet

Date: 20 Sep 85 Proj No: SWOG 8407 Status: Ongoing
 Title: Evaluation of CBDCA in Advanced Endometrial Carcinoma, Phase II

Start Date 26 Oct 84	Est Comp Date:
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC
Key Words: Endometrial Carcinoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review n/a	Results

Objective(s): 1) To determine the response rate, duration of response, and survival of patients with advanced endometrial carcinoma treated with CBDCA [1,1-cyclobutane-dicarboxylato-(2)-0,0']-(SP-4-2) platinum, NSC-241240).

2) To assess the toxicity of CBDCA in patients who have received no prior chemotherapy.

Technical Approach: Patients with histologically proven measurable metastatic or locally recurrent endometrial carcinoma are eligible for entry. Patients must have relapsed following primary treatment with surgery or radiotherapy plus surgery or have obvious metastatic disease at the time of diagnosis. All patients must have a performance status of 0-2 and an expected survival of at least six weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. No reportable data are available.

etail Summary Sheet

Date: 20 Sep 85 Proj No: SWOG 8409 Status: Ongoing
 Title: Evaluation of Fludarabine Phosphate in Refractory Multiple Myeloma,
 Phase II.

Start Date 4 Jan 85	Est Comp Date:
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC
Key Words: Multiple myeloma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review n/a	Results

Objective(s): 1) To determine the response rate and response duration to Fludarabine Phosphate in patients with refractory multiple myeloma when treated on a daily times five, every three week schedule.

2) To define the qualitative and quantitative toxicity of Fludarabine Phosphate in a Phase II setting.

Technical Approach: All patients must have a pathologically verified histologic diagnosis of multiple myeloma. Fludarabine phosphate is intended for therapy of patients with multiple myeloma who have had prior exposure to, and progression of disease on, protocols of higher priority. Patients must have measurable disease and must not have received either radiation therapy or chemotherapy for at least three weeks prior to beginning therapy with fludarabine phosphate.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. No reportable data are available at this time.

Detail Summary Sheet

Date: 19 Sep 85 Proj No: SWOG 8410 Status: Ongoing
 Title: Combination Chemotherapy of Intermediate and High-Grade Non-Hodgkin's Lymphoma with m-BACOD, Phase II

Start Date 26 Oct 84	Est Comp Date:
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC
Key Words: Non-Hodgkin's Lymphoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	5
Total Number of Subjects Enrolled to Date:	5
Date of Periodic Review n/a	Results

Objective(s): 1) To determine an approximate complete remission rate and remission duration for the treatment program of cyclophosphamide, doxorubicin, vincristine, dexamethasone, and bleomycin with intervening moderate dose methotrexate and leukovorin rescue (m-BACOD), in patients with intermediate and high grade non-Hodgkin's lymphoma.

2) To assess the feasibility of using this regimen in the Southwest Oncology Group with the intent of using m-BACOD in a future Phase III trial.

Technical Approach: Patients with biopsy proven Stage II-IV non-Hodgkin's lymphoma are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: Groupwide, 93 patients have been registered. The initial response rate appears to be quite high, in the range of 70%.

Detail Summary Sheet

Date: 19 Sep 85	Proj No: SWOG 8411	Status: Ongoing
Title: Evaluation of DTIC in Metastatic Carcinoid, Phase II.		

Start Date 26 Oct 84	Est Comp Date:
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC
Key Words: Carcinoid, metastatic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review n/a	Results

Objective(s): 1) To determine the effectiveness of dimethyl triazeno imidazole carboxamide (DTIC) in the treatment of metastatic carcinoid.

2) To determine the survival of patients with metastatic carcinoid receiving DTIC.

Technical Approach: All patients must have biopsy-prove carcinoid not amenable to further surgery. Patients must have a minimum life expectancy of 6 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. No reportable data are available at this time.

Detail Summary Sheet

Date: 19 Sep 85 Proj No: SWOG 8415 Status: Ongoing
 Title: Evaluation of Tamoxifen in Unresectable and Refractory Meningiomas, Phase II.

Start Date 26 Oct 84	Est Comp Date:
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC
Key Words: Meningioma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review n/a	Results

Objective(s): 1) To determine the antitumor activity of Tamoxifen in meningiomas not amenable to surgery or radiotherapy.

2) To estimate the response rate and response duration experienced by these patients.

Technical Approach: All patients must have a biopsy-proven diagnosis of benign meningioma and measurable disease by CT scan or NMR scan. Patients must have documented recurrence not amenable to radiation therapy or documented growth after definitive radiation therapy. Patient's tumor must be unresectable for medical or technical reasons, or have measurable residual disease.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. No reportable data are available at this time.

Detail Summary Sheet

Date: 30 Sep 85 Proj No: SWOG 8417/19 Status: Ongoing
 Title: Evaluation of Two Consolidation Regimens in the Treatment of Adult Acute Lymphoblastic Leukemia, Phase III

Start Date 27 Sep 85	Est Comp Date:
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC
Key Words: Adult acute lymphoblastic leukemia	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review n/a	Results

Objective(s): 1) To compare the effects on remission duration and survival of two consolidation regimens: the L10-M consolidation used in SWOG 8001 versus a regimen employing Daunomycin, Cytosine Arabinoside, 6-Thioguanine and escalating Methotrexate/L-Asparaginase in patients with adult acute lymphoblastic leukemia.

2) To compare the toxicities of the two consolidation regimens.

Technical Approach: All patients must have a diagnosis of acute lymphoblastic leukemia. Patients must have no evidence of serious liver or renal dysfunction defined as a bilirubin and creatinine greater than the institutional normals.

Therapy will follow the schema outlined in the study protocol.

Progress: Emergency approval was obtained to enter one patient upon this study. It is too early to report any meaningful results.

Detail Summary Sheet

Date: 19 Sep 85 Proj No: SWOG 8418 Status: Ongoing
 Title: Evaluation of Cis-Diaaminechloroplatinum in Unresectable Diffuse Malignant Mesothelioma, Phase II.

Start Date 4 Jan 85	Est Comp Date:
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC
Key Words: Mesothelioma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	0
Total Number of Subjects Enrolled to Date:	0
Date of Periodic Review n/a	Results

Objective(s): 1) To test the response rate of cis-platinum (DDP) in previously untreated patients with unresectable diffuse malignant mesothelioma.

2) To test the response rate of DDP in patients with unresectable diffuse malignant mesothelioma, previously treated with at most one prior chemotherapy program.

Technical Approach: Patients with unresectable malignant mesothelioma of pleura, peritoneum, pericardium, or paratesticular area not eligible for a higher priority Group protocol shall be eligible for this protocol. Patients must have a life expectance of six weeks or longer and performance status of 0-2.

Progress: Five patients have been entered on this study with one response to date.

Detail Summary Sheet

Date: 19 Sep 85 Proj No: SWOG 8421 Status: Ongoing
 Title: Cyclophosphamide, Methotrexate, and 5-Fluorouracil in the Treatment of Stage D₂ Adenocarcinoma of the Prostate, Phase II.

Start Date 26 Apr 85	Est Comp Date:
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC
Key Words: Adenocarcinoma, prostate	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review n/a Results	

Objective(s): To test the effectiveness and toxicity of CMF (cyclophosphamide, Methotrexate and 5-Fluorouracil) in the treatment of Stage D₂ adenocarcinoma of the prostate.

Technical Approach: All patients must have a diagnosis of histologically confirmed metastatic adenocarcinoma of the prostate. All patients must have measurable or evaluable disease and must have failed endocrine manipulation.

Progress: This is a new study. No data are available.

Detail Summary Sheet

Date: 19 Sep 85 Proj No: SWOG 8460 Status: Ongoing
 Title: Combination Chemotherapy (COPE) and Radiation Therapy for Extensive Small Cell Lung Cancer, Phase II - Pilot.

Start Date 4 Jan 85	Est Comp Date:
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC
Key Words: Small cell lung cancer	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 2	
Total Number of Subjects Enrolled to Date: 2	
Date of Periodic Review n/a	Results

Objective(s): 1) To determine the overall and complete response rates to the combination of Cyclophosphamide, VP-16 (Etoposide) and Cis-platinum followed by Vincristine, plus prophylactic or therapeutic whole brain and chest irradiation in responders in extensive small cell carcinoma of the lung.

2) To assess qualitative and quantitative toxicities of this treatment program.

3) To measure time to progression and survival of the patients treated.

Technical Approach: All patients must have a histologic diagnosis (either by bronchoscopic biopsy or surgical biopsy) or unequivocal cytologic diagnosis of undifferentiated, small cell carcinoma by light-microscopic criteria. Patients must have evidence of extensive stage disease.

Progress: Groupwise, there have been 11 registrations, with eight patients evaluable for toxicity. No unusual toxicity has been seen. Seven patients have responded.

Detail Summary Sheet

Date: 18 Sep 85 Proj No: SWOG 8461 Status: Closed
 Title: Registration and Evaluation of Patients Aged 55 and Over with
 Unfavorable Histology NHL, Phase II, Pilot

Start Date 31 Aug 84	Est Comp Date:
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators:
Key Words: Non-Hodgkin's Lymphoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 3	
Total Number of Subjects Enrolled to Date: 3	
Date of Periodic Review n/a	Results

Objective(s): 1) To determine the number of patients aged 55 and over with unfavorable histology non-Hodgkin's lymphoma who are treated at the participating institutions.

2) To determine the number of patients not entered on Southwest Oncology Group treatment protocols and the reasons why.

3) To compile baseline information on the natural history of such patients.

4) To evaluate the quality of life of these patients.

Technical Approach: Patients with Stage II-IV, histologically proven "poor prognosis" non-Hodgkin's lymphoma will be eligible. Patients must be age 55 or over.

Progress: Participating institutions were urged to register all patients over age 55.

Detail Summary Sheet

Date: 18 Sep 85 Proj No: SWOG 8490 Status: Terminated
 Title: Phase II Study of PAC (Cis-Platinum, Adriamycin, and Cyclophosphamide) in Treatment of Invasive Thymoma, Intergroup Study.

Start Date 22 Jun 84	Est Comp Date:
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators:
Key Words: Thymoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	0
Total Number of Subjects Enrolled to Date:	0
Date of Periodic Review 9 November 1984	Results Continue

Objective(s): 1) To determine the objective response rate in extensive and limited invasive thymoma treated with PAC (Cis-platinum, Adriamycin, and Cyclophosphamide).

2) To determine the duration of remission of patients with limited invasive thymoma treated with split course radiotherapy plus PAC and in patients with extensive disease treated with PAC alone.

Technical Approach: Eligible patients must have locally invasive, recurrent or metastatic thymoma.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients were entered on this study; therefore, the study was terminated.

Detail Summary Sheet

Date: 19 Sep 85 Proj No: SWOG 8491 Status: Ongoing
 Title: NCCTG #82-46-51 Controlled Phase III Evaluation of Prolonged Intra-Arterial FUDR for Selected Patients with Hepatic Metastases from Colorectal Carcinoma.

Start Date 4 Jan 85	Est Comp Date:
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC
Key Words: Colorectal carcinoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review n/a	Results

Objective(s): 1) To compare the objective tumor regression rates, time to progression, and overall survival associated with A) prolonged intra-arterial FUDG; b) loading course IV 5-FU in selected patients with hepatic metastases from colorectal carcinoma.

2) To compare the clinical tolerability of these two treatment approaches.

Technical Approach: There must be histologic documentation of an adenocarcinoma originating in the colon or rectum with unresectable hepatic metastases.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. No reportable data are available at this time.

Detail Summary Sheet

Date: 23 Sep 85 Proj No: SWOG 8492 Status: Ongoing
 Title: Radiation Therapy + 5-Fluorouracil vs. Sandwich SMF Chemotherapy +
 Radiation Therapy as Adjuvant Surgical Treatment of Pancreatic Cancer, Phase III,
 Intergroup.

Start Date 4 Dec 84	Est Comp Date:
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC
Key Words: Pancreatic cancer	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review n/a	Results

Objective(s): To compare two combined modality treatment regimens in patients with curatively resected adenocarcinoma of the exocrine pancreas with regards to duration of disease-free survival, the duration of survival, and toxicity. A pilot evaluation of "sandwich" SMF chemotherapy and radiation therapy will be performed prior to the initiation of the randomized study.

Technical Approach: All patients must have histologically confirmed adenocarcinoma of the pancreas of the ductal, acinar, or undifferentiated variety.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. No reportable data are available.

etail Summary Sheet

Date: 23 Sep 85 Proj No: SWOG 8493 Status: Ongoing
 Title: Simultaneous Cis-Platinum + Radiation Therapy Compared with Standard Therapy in the Treatment of Unresectable Squamous or Undifferentiated Carcinoma of the Head and Neck.

Start Date 26 Apr 85	Est Comp Date:
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC
Key Words: Squamous carcinoma of head and neck Undifferentiated carcinoma of head and neck	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	0
Total Number of Subjects Enrolled to Date:	0
Date of Periodic Review n/a	Results

Objective(s): 1) To compare the effectiveness of simultaneous DDP-radiation therapy with that of radiotherapy alone in improving patient survival and the disease-free interval in patients with unresectable Stage III-IV squamous cell or undifferentiated carcinoma of the head and neck.

2) To compare the toxicity of DDP-radiotherapy with that of radiotherapy alone in patients with locally advanced head and neck cancer.

3) To compare patterns of relapse or treatment failure between the two regimens.

Technical Approach: Patients must have proven histological diagnosis of squamous cell carcinoma or undifferentiated carcinoma on biopsy of the primary lesion or a neck mass. Patients will have been determined to be inoperable with locally advanced disease. Patients must have measurable disease and must be available for adequate long-term follow-up.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. No reportable data are available.

Detail Summary Sheet

Date: 23 Sep 85 Proj No: SWOG 8494 Status: Ongoing
 Title: A Comparison of Leuprolide with Flutamide and Leuprolide in Previously Untreated Patients with Clinical Stage D₂ Cancer of the Prostate, Phase III - Intergroup

Start Date 26 Apr 85	Est Comp Date:
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC
Key Words: Cancer of Prostate	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	0
Total Number of Subjects Enrolled to Date:	0
Date of Periodic Review n/a	Results

Objective(s): 1) To evaluate and compare the efficacy of the combination of Leuprolide and Flutamide versus Leuprolide alone followed at time of progression by addition of Flutamide in the treatment of newly diagnosed, previously untreated patients with metastatic (D₂) adenocarcinoma of the prostate.

2) To compare time to progression, survival, response rate and toxicity of patients treated with either treatment program.

Technical Approach: Patients initially diagnosed as having localized prostate cancer treated by radical prostatectomy or radiotherapy to prostate and pelvic lymph nodes are eligible. Patients must have bone or measurable soft tissue metastases.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. No reportable data are available.

Detail Summary Sheet

Date: 23 Sep 85 Proj No: SWOG 8503 Status: Ongoing
 Title: Combination Chemotherapy of Intermediate and High-Grade Non-Hodgkin's Lymphoma with ProMACE-CytaBOM, Phase II.

Start Date 28 Jun 85	Est Comp Date:
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC
Key Words: Non-Hodgkin's Lymphoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review n/a	Results

Objective(s): 1) To determine the complete remission rate, remission duration, and survival duration for patients with intermediate and high grade non-Hodgkin's lymphomas treated with cyclophosphamide, doxorubicin, etoposide, and prednisone followed by cytarabine, bleomycin, vincristine, and methotrexate with leukovorin (ProMACE-CytaBOM).

2) To assess the feasibility of using this regimen in the Southwest Oncology Group with the intent of using ProMACE-CytaBOM in a future Phase III trial.

Technical Approach: Patients must have Stage II-IV non-Hodgkin's lymphoma, intermediate or high-grade histology.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. No reportable data are available.

Detail Summary Sheet

Date: 23 Sep 85 Proj No: SWOG 8590 Status: Ongoing
 Title: Phase III Study to Determine the Effect of Combining Chemotherapy with Surgery and Radiotherapy for Resectable Squamous Cell Carcinoma of the Head and Neck.

Start Date 28 Jun 85	Est Comp Date:
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC
Key Words: Squamous cell carcinoma of head and neck	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review n/a	Results

Objective(s): 1) To test whether the addition of chemotherapy to surgery and radiotherapy prolongs disease-free survival and survival between the two study groups.

2) To test whether the addition of chemotherapy to surgery and radiotherapy increases local control rates at the primary site and/or the cervical neck nodes.

3) To determine if the patterns of failure have been changed with the addition of chemotherapy.

Technical Approach: Eligible patients must have histologically confirmed squamous cell carcinoma. The patient's medical condition must be such that surgery and subsequent treatment with chemotherapy and radiation are not contraindicated.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. No reportable data are available.

etail Summary Sheet

Date: 23 Sep 85 Proj No: SWOG 8591 Status: Ongoing
 Title: NCI Intergroup #0035, An Evaluation of Levamisole Alone or Levamisole plus 5-Fluorouracil as Surgical Adjuvant Treatment for Resectable Adenocarcinoma of the Colon.

Start Date 28 Jun 85	Est Comp Date:
Principal Investigator Glenn M. Mills, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Medicine/Oncology	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC
Key Words: Adenocarcinoma of colon	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	0
Total Number of Subjects Enrolled to Date:	0
Date of Periodic Review n/a	Results

Objective(s): To assess the effectiveness of levamisole alone and levamisole plus 5-fluorouracil as surgical adjuvant regimens for resectable colon cancer by comparison with untreated controls.

Technical Approach: Eligible patients must have histologic proof of adenocarcinoma taking origin in the colon. A potentially curative resection must have been performed with neither gross nor microscopic evidence of residual disease.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. No reportable data are available at this time.

Detail Summary Sheet

Date: 11 Sept 85 Proj No: GOG 26 Status: Ongoing
 Title: Master Protocol for Phase II Drug Studies in Treatment of Advanced, Recurrent Pelvic Malignancies.

Start Date FY 78	Est Comp Date:
Principal Investigator Danny R. Barnhill, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc GYN-ONC SVC. Department of Obstetrics-Gynecology	Associate Investigators:
Key Words: Malignancy, pelvic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): This protocol constitutes a Phase II design outlining the procedures that will be performed to screen for activity of new agents or drug combinations in patients with advanced recurrent pelvic malignancies. Its intent is to determine the efficacy of chemotherapeutic agents in patients whose advanced malignancies have been resistant to high priority methods of treatment.

Technical Approach: This is a study of multiple chemotherapeutic agents. Therapy will follow the schema outlined in the study protocol.
 There are ten treatment arms still open on this study. They Are: 26-C, 26-D, 26-E, 26-G, 26-N, 26-O, 26-Q, 26-S, 26-T, 26-U.

Progress: This study remains open for the study of new Phase II drugs. No patients have been entered.

Detail Summary Sheet

Date: 11 Sept 85 Proj No: GOG 34 Status: Ongoing
 Title: A Randomized Study of Adriamycin as an Adjuvant After Surgery and Radiation Therapy in Patients with High Risk Endometrial Carcinoma, Stage I, and Occult Stage II.

Start Date FY 78	Est Comp Date:
Principal Investigator Danny R. Barnhill, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc GYN-ONC SVC Department of Obstetrics-Gynecology	Associate Investigators:
Key Words: Carcinoma, endometrial	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 2	
Date of Periodic Review	Results

Objective(s): To study differences in morbidity and patient survival as functions of various tumor growth patterns as well as treatments.

Technical Approach: All patients with primary, previously untreated, histologically confirmed invasive carcinoma of the endometrium Stage I and Stage II occult, all grades, with one or more of the following high risk criteria are eligible: (1) all lesions equal to or greater than one-half myometrial involvement; (2) positive pelvic and/or para-aortic nodes; (3) microscopic evidence of cervical involvement but no gross clinical involvement of the cervix. The following types of histologically confirmed uterine carcinoma are eligible: adenocarcinoma, adenoacanthoma, adenosquamous carcinoma.

Therapy will follow the schema outlined in the study protocol.

Technical Approach: Two patients remain on the study and are responding well.

Detail Summary Sheet

Date: 11 Sept. 85 Proj No: GOG 40 Status: Ongoing
 Title: A Clinical-Pathologic Study of Stage I and II Uterine Sarcomas.

Start Date FY 79	Est Comp Date:
Principal Investigator Danny R. Barnhill, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc GYN-ONC SVC. Department of Obstetrics-Gynecology	Associate Investigators:
Key Words: Sarcoma, uterine	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To determine the incidence of pelvic and aortic lymph node metastases associated with Stage I and II uterine sarcomas, the relationship of these node metastases to other important prognostic factors such as mitotic index of the tumor, and the complication rate of the procedures.

Technical Approach: All patients with histologically proven uterine sarcoma clinical Stage I and II who are medically suitable for hysterectomy and lymphadenectomy are eligible for the study.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered on this study.

Detail Summary Sheet

Date: 11 Sept. 85 Proj No: GOG 41 Status: Ongoing
 Title: Surgical Staging of Ovarian Carcinoma.

Start Date FY 79	Est Comp Date:
Principal Investigator	Facility
Danny R. Barnhill, M.D., MAJ, MC	Brooke Army Medical Center
Dept/Svc GYN-ONC SVC.	Associate Investigators:
Department of Obstetrics-Gynecology	
Key Words:	
Carcinoma, ovarian	
Accumulative MEDCASE	Est Accumulative
Cost:	OMA Cost:
Number of Subjects Enrolled During Reporting Period:	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review	Results

Objective(s): 1) To determine the spread of ovarian carcinoma in intraperitoneal structures and retroperitoneal lymph nodes by direct examination, cytologic sampling, and biopsy.

2) To establish a surgical protocol for patients entered into GOG ovarian cancer treatment protocols.

3) To determine the complication rate of the procedures.

Technical Approach: Patients with all histologic types of primary ovarian cancer are eligible, including epithelial tumors, germ cell tumors, stromal tumors, and all others. Patients must be entered within two weeks of the last surgery.

Therapy will follow the schema outlined in the study protocol.

Progress: One patient entered on this study continues to do well.

Detail Summary Sheet

Date: 11 Sept. 85 Proj No: GOG 44 Status: Ongoing
 Title: Evaluation of Adjuvant Vincristine, Dactinomycin, and Cyclophosphamide Therapy in Malignant Germ Cell Tumors of the Ovary After Resection of All Gross Tumor, Phase III.

Start Date FY 79	Est Comp Date:
Principal Investigator Danny R. Barnhill, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc GYN-ONC SVC. Department of Obstetrics-Gynecology	Associate Investigators:
Key Words: Germ cell tumor	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): 1) To evaluate the effect of combine prophylactic vincristine, dactinomycin, and cyclophosphamide chemotherapy in patients with endodermal sinus tumor, embryonal carcinoma, immature teratoma (Grades 2 and 3), choriocarcinoma, and malignant mixed germ cell tumors of the ovary, Stages I and II after total removal of all gross tumor.

2) To evaluate the role of serum markers, especially alpha-fetoprotein (AFP) and human chorionic gonadotropin (beta HCG), when these are present, in predicting response and relapse.

3) To determine the role of restaging laparotomy in determining response, predicting relapse and planning further therapy.

Technical Approach: Patients with histologically confirmed malignant germ cell tumors of the ovary, Stage I or II, if previously untreated and completely resected, excluding patients with pure dysgerminoma unless classified as anaplastic, or eligible. Patients with grade 2 or 3 immature teratoma are also eligible. Patients with early Stage III disease will be accepted if all gross tumor is resected.

Therapy will follow the schema outlines in the study protocol.

Progress: No patients have been registered on this protocol.

Detail Summary Sheet

Date: 11 Sept 85 Proj No: GOG 45 Status: Ongoing
 Title: Evaluation of Vinblastine, Bleomycin, and Cis-Platinum in Stage III and IV and Recurrent Malignant Germ Cell Tumors of the Ovary, Phase III.

Start Date FY 79	Est Comp Date:
Principal Investigator Danny R. Barnhill, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc GYN-ONC Service Department of Obstetrics-Gynecology	Associate Investigators:
Key Words: Germ cell tumor	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review _____ Results _____	

Objective(s): To evaluate the effect of four cycles of combined Vinblastine, Bleomycin, and Cis-Platinum (VBP) chemotherapy in the management of patients with endodermal sinus tumor, embryonal carcinoma, immature teratoma (all grades), choriocarcinoma, and malignant germ cell tumors of the ovary with advanced or recurrent disease, incompletely resected.

Technical Approach: Patients with histologically confirmed malignant germ cell tumors of the ovary with advanced (Stage III-IV) or recurrent disease, incompletely resected, excluding patients with pure dysgerminoma (mature or anaplastic) are eligible. Patients with incompletely resected Stage II disease and patients previously treated with Vinblastine, Dactinomycin and Cyclophosphamide are also eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: One patient has been enrolled on this study continues to do well.

Detail Summary Sheet

Date: 11 Sept 85 Proj No: GOG 48 Status: Ongoing
 Title: A Study of Progestin Therapy and a Randomized Comparison of Adriamycin vs Adriamycin + Cyclophosphamide in Patients with Advanced Endometrial Carcinoma After Hormonal Failure, Phase III.

Start Date FY 80	Est Comp Date:
Principal Investigator	Facility
Danny R. Barnhill, M.D., MAJ, MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Obstetrics-Gynecology	
Key Words:	
Carcinoma, endometrial	
Accumulative MEDCASE	Est Accumulative
Cost:	OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): 1) To evaluate the response of advanced or recurrent endometrial carcinoma to oral progestins in patients who have received no prior hormonal therapy.

2) To compare a combination of adriamycin and cyclophosphamide to adriamycin alone as therapy for advanced or recurrent endometrial carcinoma which no longer responds to or has failed to respond to progestins in patients who have received no prior cytotoxic drugs.

Technical Approach: To be eligible for entry on this study, all patients must have documented primary Stage III, primary Stage IV, recurrent or residual endometrial adenocarcinoma, adenoacanthoma or adenosquamous carcinoma. Those patients with positive cytology as evidence of spread are eligible as non-measurable disease cases.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered on this study.

Detail Summary Sheet

Date: 11 Sept 85 Proj No: GOC 49 Status: Ongoing
 Title: A Surgical-Pathologic Study of Women with Invasive Carcinoma of the Cervix Stage IB and Randomly Assigned Radiation Therapy versus no Further Therapy in Selected Patients.

Start Date FY 81	Est Comp Date:
Principal Investigator	Facility
Danny R. Barnhill, M.D., MAJ, MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Obstetrics-Gyneology	
Key Words:	
Carcinoma, cervix	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): 1) To determine by observations of the 5-year survival and disease-free interval, the validity of current FIGO staging to the histopathologic prognostic factors of size of lesion, location of lesion, depth of invasion of tumor, histology and grade, growth pattern, and site and number of positive lymph nodes in Stage IB carcinoma of the cervix.

2) To rapidly accumulate prospectively significant surgical pathologic data which would expedite development of further protocols.

3) To determine morbidity of primary radical surgical therapy.

4) To determine if radiation therapy will improve survival in selected patients with positive nodes.

Technical Approach: All patients with primary, previously untreated, histologically confirmed, invasive carcinoma of the cervix (squamous cell, adenocarcinoma and adenosquamous) are eligible. Patients must have had a pelvic and para-aortic lymphadenectomy.

Progress: No patients have been registered on this study.

Detail Summary Sheet

Date: 11 Sept 85	Proj No: GOG 52	Status: Ongoing
Title: A Phase III Randomized Study of Cyclophosphamide plus Adriamycin plus Platinol (Cis-Platinum) vs Cyclophosphamide Platinol in Patients with Optimal Stage III Ovarian Adenocarcinoma.		

Start Date FY 81 Principal Investigator Danny R. Barnhill, M.D., MAJ, MC Dept/Svc Department of Obstetrics-Gynecology Key Words: Adenocarcinoma, ovary	Est Comp Date: Facility Brooke Army Medical Center Associate Investigators:
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	
Total Number of Subjects Enrolled to Date: 2	
Date of Periodic Review _____ Results _____	

Objective(s): To determine in "optimal" Stage III ovarian adenocarcinoma, if the addition of adriamycin to cycophosphamide plus platinol improves progression-free interval, frequency of negative second-look laparotomy and survival.

Technical Approach: Patients with proven primary Stage III ovarian adenocarcinoma (serous, mucinous, endometrioid, undifferentiated carcinoma, mixed epithelial carcinoma or clear cell) confined to the abdominal cavity and its peritoneal surfaces with residual tumor masses after surgery no larger than 1 cm in diameter are eligible. Entry must be no more than six weeks postoperative.

Therapy will follow the schema outlined in the study protocol.

Progress: Two patients entered on this study continue to do well.

Detail Summary Sheet

Date: 13 September 85	Proj No: GOG 54	Status: Ongoing
Title: Treatment of Women with Malignant Tumors of the Ovarian Stroma With Combination VCR, Dactinomycin and CTX (Phase III)		

Start Date FY 85	Est Comp Date:
Principal Investigator Danny R. Barnhill, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Gyn- Onc Service Department of Obstetrics-Gynecology	Associate Investigators:
Key Words: Ovarian Stroma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	
Total Number of Subjects Enrolled to Date:	
Date of Periodic Review	Results

- Objective(s):**
- 1) To evaluate the effectiveness of combined vincristine, dactinomycin and cyclophosphamide (VAC) in treatment of malignant tumors of the ovarian stroma in patients with residual, recurrent or advanced disease.
 - 2) To confirm completeness of response to VAC treatment with restaging laparotomy.
 - 3) To evaluate the endometrium histologically to learn more about the relationship between stromal tumors and endometrial cancer.
 - 4) To learn more about hormonal effects in patients with stromal tumors.

Technical Approach: All patients with histologically confirmed malignant tumors of the ovarian stroma not amenable to cure by further surgery or radiation therapy are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. No patients have been entered on this study.

Detail Summary Sheet

Date: 13 September 85 **Proj No:** GOG 55 **Status:** Ongoing

Title: Hormonal Contraception and Trophoblastic Sequelae after Hydatidiform Mole (Phase III).

Start Date FY 85	Est Comp Date:
Principal Investigator Danny R. Barnhill, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc GYN-ONC Service Department Obstetrics-Gynecology	Associate Investigators:
Key Words: Trophoblastic Sequelae	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): The objective of this study is to determine whether the administration of estrogen-progesterone oral contraceptives following the evacuation of a hydatidiform mole, and prior to the HCG titer reaching undetectable levels, affects the incidence of Trophoblastic sequelae requiring chemotherapy.

Technical Approach: All patients with a histologically verified diagnosis of hydatidiform mole evacuated by suction evacuation are eligible.

Progress: This is a new study. No patients have been entered on this study.

Detail Summary Sheet

Date: 11 Sept. 85 Proj No: GOG 56 Status: Ongoing
 Title: A Randomized Comparison of Hydroxyurea vs Misonidazole as an Adjunct to Radiation Therapy in Patients with Stages IIB, III, and IVA Carcinoma of the Cervix and Negative Para-Aortic Nodes.

Start Date Nov 81	Est Comp Date:
Principal Investigator Danny R. Barnhill, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Obstetrics-Gynecology	Associate Investigators:
Key Words: Carcinoma, cervix	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): 1) To determine whether hydroxyurea or misonidazole is superior as a potentiation of radiation therapy in advanced cervical cancer.

2) To compare the toxicity of hydroxyurea vs misonidazole when given concurrently with radiotherapy.

Technical Approach: All patients with primary, previously untreated histologically confirmed invasive squamous cell carcinoma of the uterine cervix, clinical stages IIB through IVA confined to the pelvis, will be eligible for this study

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been enrolled in this study.

Detail Summary Sheet

Date: 13 September 85	Proj No: GOG 57	Status: Ongoing
Title: A Randomized Comparison of Multiple Agent Chemotherapy with Methotrexate, Dactinomycin, and Chlorambucil versus the Modified Bagshawe Protocol in the treatment of "Poor Prognosis" Metastatic Gestational Trophoblastic Disease (Phase III)		

Start Date FY 85	Est Comp Date:
Principal Investigator Danny R. Barnhill, MD, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Gyn-Onc Service Department Obstetrics-Gynecology	Associate Investigators:
Key Words: Trophoblastic Disease	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): 1) To evaluate the effectiveness and toxicity of the Modified Bagshawe Protocol (MBP) in patients with "poor prognosis" metastatic gestational trophoblastic disease.

2) To compare the effectiveness and toxicity of the MBP with the standard triple agent chemotherapy with methotrexate, dactinomycin, and chlorambucil (MAC).

Technical Approach: All eligible patients with a diagnosis of gestational trophoblastic disease and an elevated HCG titer, who are considered "poor prognosis" on the basis of any of the following criteria: 1) Duration of disease greater than four months from the antecedent pregnancy. 2) Pre-treatment, 24-hour urinary HCG titer of 100,00 I.U./L or above, or serum Beta-subunit HCG-RIA titer of 42,000 mIU/ml or above. 3) Hepatic and /or cerebral metastases. 4) Metastatic gestational trophoblastic disease following term pregnancy. 5) Failure of response to prior single-agent therapy.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. No patients have been entered.

Detail Summary Sheet

Date: 11 Sept 85 Proj No: GOG 59 Status: Ongoing
 Title: A Randomized Comparison of Extended Field Radiation Therapy and Hydroxy-
 urea Followed by Cisplatin or No Further Therapy in Patients with Cervical
 Squamous Cell Carcinoma Metastatic to High Common Iliac...Lymph Nodes, Phase III.

Start Date Nov 81	Est Comp Date:
Principal Investigator Danny R. Barnhill, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Obstetrics-Gynecology	Associate Investigators:
Key Words: Carcinoma, cervix	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To determine if cis-diamminedichloroplatinum, cisplatin, given in an adjuvant setting will decrease the risk of geographic failure or improve the survival rate of progress-free interval in patients with squamous carcinoma of the cervix with metastases to high common iliac and/or para-aortic lymph nodes, proven by either histologic or cytologic means.

Technical Approach: All patients with primary, previously untreated, histologically confirmed, invasive squamous cell carcinoma of the uterine cervix, all clinical stages, with metastasis to high common iliac or para-aortic lymph nodes proven by cytologic or histologic means are eligible for this study.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been registered on this study.

Detail Summary Sheet

Date: 11 Sept. 85 **Proj No:** GOG 60 **Status:** Ongoing
Title: A Randomized Study of Doxorubicin plus Cyclophosphamide plus Cisplatin vs Doxorubicin plus Cyclophosphamide plus Cisplatin plus BCG in Patients with Advanced Suboptimal Ovarian Adenocarcinoma, Stage III and IV.

Start Date Nov 81	Est Comp Date:
Principal Investigator Danny R. Barnhill, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Obstetrics-Gynecology	Associate Investigators:
Key Words: Adenocarcinoma, ovary	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): 1) To determine if the addition of BCG to doxorubicin (adriamycin) plus cyclophosphamide plus cisplatin improves remission rate, remission duration or survival in suboptimal Stage III and IV ovarian adenocarcinoma.

2) To determine the frequency and duration of true complete remission using these regimens as judged at second-look laparotomy.

Technical Approach: Patients with established suboptimal Stage III and IV ovarian epithelial cancer are eligible. All patients must have optimal surgery and appropriate tissue for histologic evaluation, as detailed in protocol GOG 41.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered on this study.

Detail Summary Sheet

Date: 11 Sept. 85 **Proj No:** GOG 61 **Status:** Ongoing
Title: Randomized Study of Cis-platinum + Cyclophosphamide vs Hexamethylmelamine after Second-Look Surgery in Nonmeasurable Stage III Ovarian Adenocarcinoma Partially Responsive to...Cis-platinum and Cyclophosphamide.

Start Date Nov 81	Est Comp Date:
Principal Investigator Danny R. Barnhill, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Obstetrics-Gynecology	Associate Investigators:
Key Words: Adenocarcinoma, ovary	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To determine, in nonmeasurable but residual Stage III ovarian adenocarcinoma partially responsive after treatment with regimens containing cis-platinum and cyclophosphamide, if the progression-free interval and survival are improved by continuing cyclophosphamide plus cisplatinum or by changing treatment to hexamethylmelamine.

Technical Approach: Patients who have been diagnosed as Stage III ovarian cancer and who have had residual disease found at second-look laparotomy may be eligible. A patient who began with measurable disease and achieved a clinical complete response, but then at second look was found to have residual disease after treatment with regimens containing cis-platinum plus cytoxan would be eligible. A patient who originally had nonmeasurable disease and who at the time of second look has less volume of disease than was described at the time of the original surgery or in whom there has been no change in the volume of disease would be eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been registered on this study.

Detail Summary Sheet

Date: 13 September 85 **Proj No:** GOG 63 **Status:** Ongoing
Title: A Clinical-Pathological study of Stages IIB, III, and IVA Carcinoma of the Cervix

Start Date FY 85	Est Comp Date:
Principal Investigator Danny R. Barnhill, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Gyn-Onc Service Department of Obstetrics-Gynecology	Associate Investigators:
Key Words: Carcinoma, Cervix	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): 1) To evaluate the sensitivity and specificity of non-invasive procedures such as sonography, computerized axial tomography (CAT or CT), and lymphangiography in detection of metastases.

2) To better understand the significance of various surgical and pathologic factors involved in staging and therapy for "advanced" cervical cancer. The accumulated clinical/surgical/ pathological data may then play a role in modification or design of future protocols.

Technical Approach: All patients with primary, previously untreated, histologically confirmed invasive carcinoma of the uterine cervix, clinical stages IIB thorough IVA, all cell types, will be eligible for this study.

Progress: This is a new study. No patients have been entered.

Detail Summary Sheet

Date: 13 Sept 85 Proj No: GOG 64 Status: Closed
 Title: A Randomized Comparison of Rapid versus Prolonged Infusion of Cisplatin
 in Tehrapy of Squamous Cell Carcinoma of the Cervix (Phase III)

Start Date FY 85	Est Comp Date:
Principal Investigator Danny R. Barnhill, M.D., MAJ MC	Facility Brooke Army Medical Center
Dept/Svc Gyn-Oncology Service Department of Obstetrics-Gynecology	Associate Investigators:
Key Words: Squamous Cell Carcinoma, Cervix	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____ Results _____	

Objective(s): 1) To determine whether the frequency and duration of objective response of squamous cell carcinoma of the cervix is altered significantly by prolonging to 24 hours the duration of the infusion of a dose of cisplatin, as compared to administration at a rate of 1 milligram per minute.

2) To determine whether administration of a dose of cisplatin as a continuous 24-hour infusion alters the frequency and/or severity of drug-related nausea and vomiting, as compared to administration of the same dose at a rate of 1 milligram per minute.

Technical Approach: Patients who have histologically confirmed, locally advanced, recurrent, persistent, or metastatic squamous cell carcinoma of the cervix, which is resistant to curative treatment with surgery or radiotherapy.

Progress: This study was closed by GOG before any patients were enrolled.

Detail Summary Sheet

Date: 13 Sept 85	Proj No: GOG 66	Status: Ongoing
Title: Ultrastructural, Staging, and Therapeutic Considerations in Small Cell carcinoma of the Cervix (Phase II)		

Start Date FY 85 Principal Investigator Danny R. Barnhill, M.D., MAJ, MC Dept/Svc Department of Obstetrics - Gynecology Key Words: Small Cell Carcinoma, Cervix	Est Comp Date: Facility Brooke Army Medical Center Associate Investigators:
Accumulative MEDCASE Cost: Number of Subjects Enrolled During Reporting Period: Total Number of Subjects Enrolled to Date: Date of Periodic Review _____	Est Accumulative OMA Cost: _____ _____ Results _____

Objective(s):

- 1) To determine the incidence of neuroendocrine carcinoma of the cervix in cases which are histologically classified as small cell carcinoma.
- 2) To determine the response rate to combination chemotherapy in patients with Stage IVB small cell carcinoma of the cervix and in patients with progressive local disease after radiation therapy.

Technical Approach: Patients with histologic diagnosis of small cell carcinoma of the cervix. A patient who has small cell carcinoma mixed with large cell keratinizing carcinoma or adenocarcinoma is eligible, providing that the small cell elements comprise 50 percent of the tumor. Only patients with primary Stage IVB disease (clinical or surgical) or recurrence in the pelvis after radiation therapy are eligible for chemotherapy after this study. Chemotherapy patients must have measurable disease (in two dimensions perpendicular to each other, by palpation or by an appropriate x-ray and/or ultra sound procedure.

Progress: This is a new study. No patients have been entered.

Detail Summary Sheet

Date: 11 Sept 85 Proj No: GOG 70 Status: Ongoing
 Title: A Randomized Comparison of Single-Agent Chemotherapy, Methotrexate and Methotrexate with Folinic Acid Rescue, in "Good Prognosis" Metastatic Gestational Trophoblastic Disease, Phase III.

Start Date 25 Sep 84	Est Comp Date:
Principal Investigator Danny R. Barnhill, M.D., MAJ, MC	Facility Brooks Army Medical Center
Dept/Svc Department of Obstetrics-Gynecology	Associate Investigators:
Key Words: Trophoblastic disease	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____ Results _____	

Objective(s): 1) To judge the relative efficacy of scheduling variation in the chemotherapeutic management of "good prognosis" metastatic trophoblastic disease.

2) To ascertain the relative toxicities of the two regimens.

Technical Approach: To be eligible for this study, patients must have metastatic gestational trophoblastic disease who are "good prognosis" with: 1) antecedent molar pregnancy, ectopic pregnancy, or abortion; 2) duration of disease less than 4 months from antecedent pregnancy; 3) metastatic disease present but no liver or brain metastasis. All patients must have had pelvic ultrasound to exclude intrauterine pregnancy.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been registered on this study.

Detail Summary Sheet

Date: 13 Sept 85		Proj No: GOG 71		Status: Ongoing	
Title: Treatment of Patients with Sub-Optimal ("Bulky") Stage IB Carcinoma of the Cervix: A Randomized Comparison of Radiation Therapy Versus Radiation Therapy plus Adjuvant Extrafascial Hysterectomy (Phase III)					
Start Date FY 85			Est Comp Date:		
Principal Investigator Danny R. Barnhill, M.D., MAJ, MC			Facility Brooke Army Medical Center		
Dept/Svc Department of Obstetrics-Gynecology			Associate Investigators:		
Key Words: Carcinoma, Cervix					
Accumulative MEDCASE Cost:			Est Accumulative OMA Cost:		
Number of Subjects Enrolled During Reporting Period: _____					
Total Number of Subjects Enrolled to Date: _____					
Date of Periodic Review _____ Results _____					

Objective(s): 1) Evaluation of the role of adjunctive extrafascial hysterectomy in the treatment of suboptimal Stage IB carcinoma of the cervix with negative para-aortic and high common iliac nodes. 2) Evaluation of survival and patterns of failure in suboptimal IB cervical cancer. 3) The study of toxicity of a combined radiation and surgical therapeutic program. 4) Evaluation of the prognostic value of various surgical/pathological characteristics in suboptimal Stage IB carcinoma of the cervix. 5) To estimate the prevalence of various disease characteristics (e.g., positive para-aortic nodes) in suboptimal Stage IB carcinoma of the cervix.

Technical Approach: Patients with primary, untreated, histologically confirmed invasive carcinoma of the uterine cervix, suboptimal or bulky, FIGO Stage IB, as confirmed by cervical biopsy and endometrial sampling are eligible for this study. Treatment will follow that outlined in the study schema.

Progress: This is a new study. No patients have been entered.

Detail Summary Sheet

Date: 11 Sept 85	Proj No: GOG 72	Status: Ongoing
Title: Ovarian Tumors of Low Malignant Potential: A Study of the Natural History and a Phase II Trial of Melphalan and Secondary Treatment with Cisplatin.		

Start Date 25 Sep 84	Est Comp Date:
Principal Investigator Danny R. Barnhill, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Obstetrics-Gynecology	Associate Investigators:
Key Words: Cancer, ovary	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): 1) To evaluate the biologic behavior of ovarian tumors of low malignant potential.

2) To evaluate the effectiveness of chemotherapy against this disease; initially, a Phase II study of melphalan.

3) To evaluate the response rate to cisplatin in melphalan failures.

Technical Approach: All patients with ovarian tumors considered to be in the pathology classification of low malignancy potential are eligible. Patients must have undergone adequate surgical staging and any stage of disease from I-IV inclusive.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been registered on this study

Detail Summary Sheet

Date: 13 Sept. 85	Proj No: GOG 73	Status: Ongoing
Title: A Clinicopathologic Study of Primary Malignant Melanoma of the Vulva Treated by Modified Radical Hemivulvectomy		

Start Date FY 85	Est Comp Date:
Principal Investigator Danny R. Barnhill, M.D., MAJ MC	Facility Brooke Army Medical Center
Dept/Svc Department of Obstetrics-Gynecology	Associate Investigators:
Key Words: Melanoma, Vulva	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review	Results

Objective(s): 1) To determine the relationship of histopathologic parameters (including microstaging of primary malignant melanoma of the vulva) to FIGO staging, nodal status and ultimate prognosis.

2) To ultimately recommend appropriate therapy for malignant melanomas of the vulva based on histopathologic and microstaging data.

Technical Approach: All patients receiving primary therapy for primary malignant melanoma of the vulva, including all histopathologic types and differentiation, and all FIGO stages. All patients must have at least a modified radical hemivulvectomy, as well as entered within 8 weeks of initiation of primary therapy.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. No patients have been entered on this study.

Detail Summary Sheet

Date: 13 September 85	Proj No: GOG 74	Status: Ongoing
Title: Early Stage I Vulvar Carcinoma Treated with Ipsilateral Superficial Inguinal Lymphadenectomy and Modified Radical Hemivulvectomy (Phase II)		

Start Date FY 85	Est Comp Date:
Principal Investigator Danny R. Barnhill, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Obstetrics-Gynecology	Associate Investigators:
Key Words: Carcinoma, Vulvar	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review	Results

Objective(s): 1) To document the rates and patters of recurrence of patients with early Stage I vulvar carcinoma treated with ipsilateral superficial inguinal lymphadenectomy and modified radical hemivulvectomy. 2) To document the survival and recurrence-free interval in the same group of patients.

Technical Approach: All patients with primary, untreated, hitologically confirmed squamous cell carcinoma of the vulva, Stage I, will be eligible for surgical treatment as " early superficially invasive carcinoma of the vulva" if: 1) a wide local excision with normal skin margins greater than 2 cm be performed. 2) There is only a single malignant lesion which measures 2 cm or less by largest diameter in vivo.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. No patients have been entered on this study.

Detail Summary Sheet

Date: 13 September 85 **Proj No:** GOG 75 **Status:** Ongoing
Title: Postoperative Pelvic Radiation in Stage I and II Mixed Mesodermal Tumors of the Uterus (Phase III)

Start Date FY 85	Est Comp Date:
Principal Investigator Danny R. Barnhill, MD, MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Obstetrics-Gynecology	Associate Investigators:
Key Words: Mesodermal Tumors, Uterus	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review	Results

Objective(s): To determine whether pelvic postoperative radiation therapy will decrease local and regional recurrence rates and improve median progression-free interval in patients with Stage I and II mixed mesodermal sarcomas of the uterus.

Technical Approach: Patients with primary clinical Stage I and II mixed mesodermal tumors of the uterus who have been entered on Protocol 40 and found to have disease confined to the pelvis which has been grossly resected.

Randomization and therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. No patients have been entered on this study.

Detail Summary Sheet

Date: 11 Sept. 85 **Proj No:** GOG 78 **Status:** Ongoing
Title: Evaluation of Adjuvant Vinblastine, Bleomycin and Cisplatin Therapy in Totally Resected Choriocarcinoma, Endodermal Sinus Tumor, or Embryonal Carcinoma of the Ovary.

Start Date 25 Sep 84	Est Comp Date:
Principal Investigator Danny R. Barnhill, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Obstetrics-Gynecology	Associate Investigators:
Key Words: Carcinoma, ovary	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): 1) To evaluate the effect of adjuvant vinblastine, bleomycin, and cisplatin (VBP) chemotherapy in patients with endodermal sinus tumor and choriocarcinoma of the ovary (pure and mixed) after removal of all gross tumor.

2) To evaluate the role of serum markers, especially alpha fetoprotein (AFP), and human chorionic gonadotropin (HCG) when these are present initially in predicting recurrence.

3) To evaluate the role of reassessment laparotomy in determining response, detecting early relapse and planning further therapy.

4) To compare the biologic behavior of pure endodermal sinus tumors with mixed germ cell tumors containing endodermal sinus elements.

Technical Approach: Patients with histologically confirmed Stage I choriocarcinoma, endodermal sinus tumor or embryonal carcinoma of the ovary, pure or mixed with other elements, if totally resected are eligible. Patients with Stage II and Stage III disease are also eligible if all gross tumor has been resected. The serum AFP and beta-HCG levels should be normal or falling at a rate that does not suggest residual disease.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been registered on this study.

Detail Summary Sheet

Date: 13 September 85 **Proj No:** GOG 79 **Status:** Ongoing
Title: Single Agent Weekly Methotrexate Therapy in the Treatment of Nonmetastatic Gestational Trophoblastic Disease

Start Date FY 85	Est Comp Date:
Principal Investigator Danny R. Barnhill, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Obstetrics - Gynecology	Associate Investigators:
Key Words: Gestational Trophoblastic Disease, nonmetastatic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review	Results

Objective(s): 1) To determine the efficacy of weekly methotrexate therapy for nonmetastatic gestational trophoblastic disease. 2) To ascertain the toxicity of this regimen. 3) To demonstrate the cost effectiveness of this regimen.

Technical Approach: Patients with nonmetastatic gestational trophoblastic disease with antecedent molar pregnancy of post-abortion status who meet the criteria outlined in Section 3.11 of the study protocol.

Randomization and therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. No patients have been entered on this study.

Detail Summary Sheet

Date: 11 Sept 85	Proj No: 7602	Status: Ongoing
Title: Ovarian Cancer Study Group Protocol for All Stage IC and II (A,B,C) and Selected Stage IAii and IBii Ovarian Cancer.		

Start Date FY 79	Est Comp Date:
Principal Investigator Danny R. Barnhill, M.D., MAJ, MC	Facility Brooke Army Medical Center
Dept/Svc GYN-ONC Service Department of Obstetrics-Gynecology	Associate Investigators:
Key Words: Cancer, ovary	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review	Results

Objective(s): 1) To define the natural history (relapse rate, relapse sites, relapse free survival, regression rate, duration of regression) of patients treated by surgery plus either chemotherapy or chemotherapy plus radiation therapy.

2) To study the effect of various potential prognostic factors (stratification factors) on the natural history of patients treated by each form of therapy.

Technical Approach: All eligible patients must have a histopathologic diagnosis of common epithelial ovarian cancer of one of the following types: serous, mucinous or one of the types identified in Appendix I of the study protocol. After a definitive staging procedure, if the patient is Stage II-A, II-B, II-C, I-Aii, I-Bii, or I-Ai or I-Bi with poorly differentiated tumors, she is eligible for the study. The patient must have had no previous treatment except surgical therapy.

Randomization and therapy will follow the schema outlined in the study protocol.

Progress: One patient has been enrolled on this study and continues to do well.

Detail Summary Sheet

Date: 23 Oct 85 Proj No: POG 7799 Status: Ongoing
 Title: Rare Tumor Registry for Childhood Solid Tumor Malignancies

Start Date 25 Sep 81	Est Comp Date:
Principal Investigator Terry E. Pick, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Solid tumor malignancies	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review n/a	Results

Objective(s): 1) To collect natural history data on malignancies which occur so rarely that large series of patients cannot be accumulated any single institution.

2) To evaluate therapies in those groups of rare tumors in which fair numbers of cases can be accrued.

Technical Approach: Any child under the age of 18 years at diagnosis with a rare solid tumor is eligible for the study.

Progress: One patient remains on this study. No reportable data are available.

Detail Summary Sheet

Date: 23 Oct 85 Proj No: POG 7837 Status: Ongoing
 Title: Evaluation of Systemic Therapy for Children with T-Cell Acute Lymphatic Leukemia, Phase III.

Start Date 25 Sep 81	Est Comp Date:
Principal Investigator Terry E. Pick, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Leukemia, acute lymphatic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 3	
Total Number of Subjects Enrolled to Date: 6	
Date of Periodic Review 24 Dec 84	Results Continue

Objective(s): To evaluate the effectiveness of a program of sequential systemic chemotherapy plus CNS treatment for children with untreated T-cell leukemia.

Technical Approach: Patients under the age of 21 with a diagnosis of T-cell leukemia as defined by SWOG 7865 including all patients who have 20% or greater E-rosetting leukemia cells are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: Four patients remain on the study. All are doing well.

Detail Summary Sheet

Date: 23 Oct 85	Proj No: POG 7898	Status: Closed
Title: Intergroup Study of Rhabdomyosarcoma - II		

Start Date 5 Mar 84	Est Comp Date:
Principal Investigator Terry E. Pick, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Rhabdomyosarcoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 14 December 1984 Results Closed	

Objective(s): To compare two forms of treatment, the duration of disease control, and side effects of the treatment program.

Technical Approach: Patients under 21 years of age with the diagnosis of rhabdomyosarcoma (any of the four cellular types plus the special undifferentiated types and small cell mesenchymal sarcoma) or undifferentiated sarcoma, type indeterminate, are eligible for this study.

Therapy will follow the schema outlined in the study protocol.

Progress: This study has been closed to new entries.

Detail Summary Sheet

Date: 23 Oct 85 Proj No: POG 7901 Status: Ongoing
 Title: Rescue Therapy for Non-CNS Extramedullary Disease in Children with Acute Lymphoblastic Leukemia, Phase III

Start Date 27 Jan 83	Est Comp Date:
Principal Investigator Terry E. Pick, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Leukemia, acute lymphoblastic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: 2	
Date of Periodic Review 14 December 1985 Results Continue	

Objective(s): To administer effective local therapy for non-CNS extramedullary disease occurring during marrow remission or marrow relapse in children with acute lymphocytic leukemia (ALL).

Technical Approach: Children less than 21 years of age at time of diagnosis, with ALL are eligible for EMD "rescue" therapy when the diagnosis of EMD has been established.

Therapy will follow the schema outlined in the study protocol.

Progress: Two patients remain on the study. No reportable data are available.

Detail Summary Sheet

Date: 23 Oct 84	Proj No: POG 7909	Status: Ongoing
Title: Evaluation of MOPP Adjuvant Chemotherapy in the Treatment of Localized Medulloblastoma and Ependymoma.		

Start Date May 81	Est Comp Date:
Principal Investigator Terry E. Pick, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Medulloblastoma Ependymoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 2	
Date of Periodic Review 14 December 1985 Results Continue	

Objective(s): To evaluate the efficacy and toxicity of the MOPP adjuvant chemotherapy in the prevention of local recurrence of distant metastasis in children with localized medulloblastoma and ependymoma.

Technical Approach: Patients between 1 and 21 years (inclusive) with histologically proven medulloblastoma and ependymoma are eligible for the study.

Therapy will follow the schema outlined in the study protocol.

Progress: Two patients have been entered into this study. Both have responded fairly well to therapy.

Detail Summary Sheet

Date: 23 Oct 85 Proj No: POG 8000[^] Status: Ongoing
 Title: National Wilms' Tumor Study, III

Start Date 25 Sep 81	Est Comp Date:
Principal Investigator Terry E. Pick, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Wilms' tumor	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 2	
Total Number of Subjects Enrolled to Date: 4	
Date of Periodic Review 14 December 1984 Results Continue	

- Objective(s): 1) To gain better understanding of Wilms' tumor by gathering detailed information regarding gross and histologic morphology.
- 2) To refine methods of treatment according to staging.
- 3) To test treatment hypotheses by randomized prospective clinical trials according to stage and histologic grade of disease.
- 4) To gather information about family cancer in an attempt to identify children and families at high risk.
- 5) To study the late consequences of successful treatment given for Wilms' tumor.

Technical Approach: Patients under the age of 15 with Wilms tumor are eligible.

Progress: Two patients remain on this study and are doing well.

Detail Summary Sheet

Date: 23 Oct 85 Proj No: POG 8035-6 Status: Ongoing
 Title: Laboratory Subclassification and Evaluation of Treatment Regimens in
 Acute Lymphoid Leukemia of Childhood.

Start Date 27 Jan 83	Est Comp Date:
Principal Investigator Terry E. Pick, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Leukemia, lymphoid	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 12	
Total Number of Subjects Enrolled to Date: 18	
Date of Periodic Review 14 December '84 Results Continue	

Objective(s): 1) To determine if adding a high dose of a standard chemotherapy agent used in acute lymphocytic leukemia every 8 weeks and maintenance increases the chance of survival over the regular doses of standard chemotherapy drugs in the "good risk" patient.

2) To determine if one of three treatment regimens is better in treating the "poor risk" patient.

Technical Approach: Eligible patients will receive one of three treatment regimens. Regimen 1 consists of standard drugs given in the usual fashion with triple intrathecal medications given in the spinal fluid to prevent CNS leukemia for three years. Regimen 2 consists of the standard chemotherapy agents plus high dose Methotrexate pulses during maintenance with triple intrathecal medications given in consolidation, and low dose intrathecal Methotrexate given for one year. Regimen 3 consists of pulses of a variety of courses of different agents that are superimposed upon the routine maintenance therapy plus triple intrathecal medications for three years to determine if these pulses of different chemotherapy agents can improve the outcome of this high risk group.

Progress: Twelve patients remain on the study and thus far seem to be responding to therapy.

Detail Summary Sheet

Date: 23 Oct 85 Proj No: POG 8080 Status: Ongoing
 Title: Classification of T-Cell Non-Hodgkin Lymphomas and Acute Leukemias into Subgroups Based on Immunologic Cell Surface Characteristics.

Start Date 25 Sep 84	Est Comp Date:
Principal Investigator Terry E. Pick, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Lymphoma, non-Hodgkin Leukemia	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 2	
Total Number of Subjects Enrolled to Date: 2	
Date of Periodic Review 14 December 1985 Results Continue	

Objective(s): 1) To compare marker data for T-leukemias with that from T-lymphomas to determine whether these entities represent clearly separate diseases, by immunological criteria, or whether they represent different clinical presentations of the same disease process.

2) To correlate the presence or absence of cell markers with clinical characteristics: age, sex, white count, organ involvement, etc., to determine whether any marker or immunologic T-subset may carry clinical prognostic significance.

Technical Approach: All newly diagnoses cases of acute lymphoblastic T-cell leukemia, with no previous chemotherapy, are eligible. Patients with non-Hodgkin lymphoma presenting with non-abdominal primary sites are likewise eligible.

Therapy for patients entered onto this study will be according to the Pediatric Oncology Group protocol priority.

Progress: Two patients have been enrolled on the study. No reportable data are available.

Detail Summary Sheet

Date: 23 Oct 85 Proj No: POG 8101 Status: Ongoing
 Title: Acute Nonlymphocytic Leukemia in Children, Phase III.

Start Date 27 Dec 83	Est Comp Date:
Principal Investigator Terry E. Pick, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Leukemia, nonlymphocytic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 2	
Total Number of Subjects Enrolled to Date: 2	
Date of Periodic Review 14 December 1984 Results Continue	

Objective(s): 1) To compare the remission rate and toxicity data of an intensive 3-drug regimen for acute nonlymphocytic leukemia (ANLL), utilizing cytosine arabinoside, Daunomycin and 6-thioguanine, with that observed using an anthracycline-free induction regimen that employs an identical schedule of cytosine arabinoside, but combined with vincristine and dexamethasone. To determine the effect, if any, of the induction regimen on remission duration.

2) To accumulate clinical and laboratory data regarding features present at diagnosis of ANLL, to relate this information to the behavior of the disease(s) under treatment, and to establish the natural history of the disease.

Technical Approach: Patients under 21 years of age presenting with the diagnosis of acute leukemia other than lymphoblastic are eligible. Randomization for the induction regimen will be by disease category (AML, AMML, APL, and other). All patients with APL will be placed on the anthracycline-containing induction and maintenance arms.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients remain on this study due to poor response.

Detail Summary Sheet

Date: 23 Oct 85 Proj No: POG 8104 Status: Ongoing
 Title: Comprehensive Care of the Child with Neuroblastoma: A Stage and Age Oriented Study, Phase III.

Start Date 27 Jan 83	Est Comp Date:
Principal Investigator Terry E. Pick, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Neuroblastoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 5	
Total Number of Subjects Enrolled to Date: 7	
Date of Periodic Review 14 December 1984 Results Continue	

Objective(s): 1) To treat the tumor according to age and stage at which the tumor was diagnosed.

2) To reduce later complications by separating by age and stage those patients that require surgery only; surgery and chemotherapy; surgery, chemotherapy, and radiation therapy.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Five patients remain on the study and are responding fairly well.

Detail Summary Sheet

Date: 23 Oct 85	Proj No: POG 8106	Status: Ongoing
Title: High-Dose Cyclophosphamide/High-Dose Methotrexate with Coordinated Triple Intrathecal Therapy for Stages III and IV Nonlymphoblastic Lymphoma, Phase III.		
Start Date 27 Dec 83	Est Comp Date:	
Principal Investigator Terry E. Pick, M.D., LTC, MC	Facility Brooke Army Medical Center	
Dept/Svc Department of Pediatrics	Associate Investigators:	
Key Words: Lymphoma, nonlymphoblastic		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	
Number of Subjects Enrolled During Reporting Period: 2		
Total Number of Subjects Enrolled to Date: 2		
Date of Periodic Review 14 December 1984 Results Contine		

Objective(s): 1) To determine complete remission rates, remission lengths and survival times for children with Murphy's Stages III and IV, diffuse nonlymphoblastic lymphomas using combination chemotherapy consisting of a vigorous prophylactic IT regimen, conventional doses of vincristine sulfate (VCR) and prednisone(Pred) and high doses of cyclophosphamide (CYT) and methotrexate (MTX) intravenously.

2) To document the toxicity and complications of this therapy.

Technical Approach: Patients under 21 years of age, newly diagnosed with Stage III or IV diffuse nonlymphoblastic lymphoma who have never received therapy are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: Two patients have been entered on this study. No reportable data are available at this time.

Detail Summary Sheet

Date: 17 Oct 85 Proj No: POG 8107 Status: Ongoing
 Title: Multi-Institutional Controlled Trial of Adjuvant Chemotherapy in the Treatment of Osteosarcoma, Phase III.

Start Date 27 Sep 85	Est Comp Date:
Principal Investigator	Facility
Terry E. Pick, M.D., LTC, MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Pediatrics	
Key Words:	
Osteosarcoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review n/a	Results

Objective(s): 1) To determine if intensive multi-agent chemotherapy given adjuvantly after surgical ablation of the primary tumor will significantly improve the disease-free survival (DFS) for patients with non-metastatic osteosarcoma when compared to a concurrent, non-adjuvantly treated control group.

2) To determine if freedom from second relapse and overall survival are different for patients treated with immediate postoperative adjuvant chemotherapy versus those treated with delayed adjuvant chemotherapy after relapse and metastasectomy.

Technical Approach: All patients with previously untreated osteosarcoma are eligible. The patient must have no metastases at diagnosis, determined by physical exam, chest CT scan, and bone scan.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.

Detail Summary Sheet

Date: 17 Oct 85 Proj No: POG 8261 Status: Ongoing
 Title: Evaluation of Response and Toxicity of VP-16-213 in Children with
 Recurrent Malignant Solid Tumors Unresponsive to Standard Therapy, Phase II.

Start Date 27 Sep 85	Est Comp Date:
Principal Investigator Terry E. Pick, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Solid tumors	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review n/a	Results

Objective(s): 1) To evaluate the spectrum of anti-tumor activity of VP-16 in patients with solid tumors, resistant to conventional chemotherapy.

2) To evaluate the toxicity of VP-16 in patients with solid tumors.

3) To document the response rate to VP-16 in patients with recurrent malignant solid tumors.

Technical Approach: Patients under 21 years of age with malignant solid tumors, and measurable lesions no amenable to standard therapy, with a life expectancy of greater than 8 weeks, who do not have an uncontrolled serious infection, and who have an adequate nutritional status are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.

Detail Summary Sheet

Date: 23 Oct 85	Proj No: POG 8303	Status: Ongoing
Title: Combination Chemotherapy for First Bone Marrow and/or Testicular Relapse of Childhood Acute Lymphoblastic Leukemia (ALL) During or Shortly Following Initial Continuation Therapy, Phase III.		
Start Date 27 Dec 83	Est Comp Date:	
Principal Investigator	Facility	
Terry E. Pick, M.D., LTC, MC	Brooke Army Medical Center	
Dept/Svc	Associate Investigators:	
Department of Pediatrics		
Key Words:		
Leukemia, lymphoblastic		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	
Number of Subjects Enrolled During Reporting Period: 1		
Total Number of Subjects Enrolled to Date: 1		
Date of Periodic Review 14 December 1984 Results Continue		

Objective(s): 1) To determine if intensive early therapy with a 4-drug reinduction regimen immediately followed by consolidation therapy is more effective than reinduction regimens used in the past for patients with ALL or lymphoblastic lymphoma who relapse on or shortly following termination of initial continuation therapy.

2) To assess the efficacy and toxicity of continuous and alternating maintenance therapy during second remission with 2 drug pairs not used during first remission: VM-26 plus Ara-C and vincristine plus cyclophosphamide.

3) To determine the effectiveness and toxicity of periodic 4 drug reinduction therapy (reinforcement) throughout second remission.

Technical Approach: Patients less than 21 years of age who develop their first marrow relapse or overt clinical testicular relapse during initial continuation chemotherapy are eligible. Children with CNS relapse accompanying marrow and/or testicular relapse are also eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: One patient has been entered on this study; however, it is too early to report any meaningful results.

Detail Summary Sheet

Date: 23 Oct 85	Proj No: POG 8304	Status: Ongoing
Title: SIMAL #4. Combination Chemotherapy for Remission Induction and Maintenance for: 1) Recurrent Childhood Lymphocytic Leukemia After Elective Cessation of Therapy; 2) Children with Occult Testicular Leukemia After 3 Years of Continuous Complete Remission.		
Start Date 27 Jan 84	Est Comp Date:	
Principal Investigator Terry E. Pick, M.D., LTC, MC	Facility Brooke Army Medical Center	
Dept/Svc Department of Pediatrics	Associate Investigators:	
Key Words: Leukemia, lymphocytic		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	
Number of Subjects Enrolled During Reporting Period: _____		
Total Number of Subjects Enrolled to Date: _____		
Date of Periodic Review 14 December 1984 Results Continue		

Objective(s): 1) To compare the effectiveness of two regimens of cyclic maintenance chemotherapy in children with ALL, who relapse 6 months or greater, after elective cessation of chemotherapy.

2) To evaluate the effectiveness of prophylactic intrathecal chemotherapy, during the second remission.

3) To compare the effectiveness of two regimens of cyclic maintenance chemotherapy in patients with testicular leukemia.

4) To determine the effectiveness of two regimens of cyclic maintenance chemotherapy in children with isolated CNS relapse.

Technical Approach: Patients less than 21 years of age with pathologic verification of leukemic relapse at any site more than six months after elective cessation of initial therapy are eligible. Children with their first CNS relapse are also eligible for this study.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. No patients have been entered.

Detail Summary Sheet

Date: 23 Oct 85 Proj No: POG 8306 Status: Ongoing
 Title: Study of MTX Pharmacology During ALL Maintenance Therapy.

Start Date 27 Mar 84	Est Comp Date:
Principal Investigator Terry E. Pick, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Leukemia, lymphocytic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 4	
Total Number of Subjects Enrolled to Date: 4	
Date of Periodic Review 14 December 1984 Results Continue	

Objective(s): To determine whether the levels of red cell MTX and folate in patients on therapy for ALL can be correlated with remission duration.

Technical Approach: All newly diagnosed patients with acute lymphatic leukemia are eligible. Blood samples will be obtained and checks for Methotrexate levels.

Progress: Four patients have been entered on this study. No reportable data are available at this time.

Detail Summary Sheet

Date: 23 Oct 85 Proj No: POG 8315 Status: Ongoing
 Title: Laboratory Study and Subclassification of Non-Hodgkin's Lymphoma.

Start Date 25 Sep 84	Est Comp Date:
Principal Investigator	Facility
Terry E. Pick, M.D., LTC, MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Pediatrics	
Key Words:	
Lymphoma, Non-Hodgkin's	
Accumulative MEDCASE	Est Accumulative
Cost:	OMA Cost:
Number of Subjects Enrolled During Reporting Period:	
Total Number of Subjects Enrolled to Date:	
Date of Periodic Review	Results

Objective(s): 1) To provide a mechanism for the group wide study of biologic characteristics of lymphoma cells, by acquisition and coordination of data from reference laboratories.

2) To seek correlates of biologic characteristics, with histopathology, clinical presentation, and end results of protocol therapies.

3) To attempt the development of a comprehensive classification of childhood NHL which is both clinically and biologically relevant.

Technical Approach: Patients less than 21 years of age with tumor tissue or cells available for study who are simultaneously being entered on open, front-end POG treatment protocols for NHL are eligible for this study.

Progress: This is a new study. No patients have been entered.

Detail Summary Sheet

Date: 23 Oct 85 Proj No: POG 8319 Status: Ongoing
 Title: Allogeneic Bone Marrow Transplantation for Acute Lymphoblastic Leukemia
 in 2nd Hematologic Remission.

Start Date 27 Mar 84	Est Comp Date:
Principal Investigator	Facility
Terry E. Pick, M.D., LTC, MC	Brooke Army Medical Center
Dept/Svc	Associate Investigators:
Department of Pediatrics	
Key Words:	
Leukemia, lymphoblastic	
Accumulative MEDCASE	Est Accumulative
Cost:	OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review 14 December 1984 Results Continue	

Objective(s): To study the feasibility of cytosine arabinoside (ara-C), used in high dosage in conjunction with fractionated total body irradiation, followed by allogeneic or syngeneic bone marrow transplantation, in achieving long-term disease-free survival of children with acute lymphoblastic leukemia in second hematologic remission.

Technical Approach: Patients less than 21 years of age with a diagnosis of ALL verified by examination of diagnostic bone marrow, who have suffered their first bone marrow relapse while on therapy with an established POG ALL frontline protocol are eligible. Patients will be in complete remission, without evidence of leukemia either in the bone marrow or estramedullary sites.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered on this study.

Detail Summary Sheet

Date: 23 Oct 85	Proj No: POG 8336	Status: Ongoing
Title: Evaluation of Response and Further Determination of Toxicity with Aziridinybenzoquinone (AZQ) in Children and Adolescents with Malignant Solid Tumors Resistant to Standard Therapy, Phase II.		
Start Date 27 Jan 84	Est Comp Date:	
Principal Investigator	Facility	
Terry E. Pick, M.D., LTC, MC	Brooke Army Medical Center	
Dept/Svc	Associate Investigators:	
Department of Pediatrics		
Key Words:		
Solid tumors		
Accumulative MEDCASE	Est Accumulative	
Cost:	OMA Cost:	
Number of Subjects Enrolled During Reporting Period: _____		
Total Number of Subjects Enrolled to Date: _____		
Date of Periodic Review 14 December 1984 Results Continue		

Objective(s): 1) To evaluate the response rate and duration of response to AZQ given to children with recurrent brain and other solid tumors resistant to standard therapy.

2) To further assess the toxicity of AZQ in children.

Technical Approach: Patients under 21 years of age who have recurrent brain tumors with a measurable lesion by CT scan, or other solid tumors (with measurable lesions) resistant to standard methods of therapy, are eligible. Patients must have a life expectancy of greater than six weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered on this study.

Detail Summary Sheet

Date: 13 Oct 85 Proj No: POG 8340 Status: Ongoing
 Title: Allogeneic or Autologous Bone Marrow Transplantation (BMT) for Stage D Neuroblastoma: A POG Pilot Study

Start Date 12 Aug 85	Est Comp Date:
Principal Investigator Terry E. Pick, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics/Medicine	Associate Investigators: Walter H. Harvey, D.O., MAJ, MC John J. Posch, Jr. Barbara Reeb
Key Words: Transplantation, bone marrow, autologous	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 2	
Total Number of Subjects Enrolled to Date: 2	
Date of Periodic Review	Results

Objective(s): 1) To determine the response rate and duration of patients aged > 1 year with metastatic (Stage D) neuroblastoma to intensive chemotherapy and fractionated total body irradiation followed by allogeneic or autologous bone marrow transplantation (BMT) performed in first clinical remission.

2) To determine the response rate and duration using the same regimen in patients with Stage D neuroblastoma who fail to respond to, or recur after, conventional chemotherapy.

3) To determine the toxicity of the above regimen.

Technical Approach: This pilot study tests the efficacy and toxicity of high dose melphalan and fractionated total body irradiation supported by allogeneic or autologous BMT for neuroblastoma in first clinical remission or following relapse.

Bone marrow aspiration and therapy will follow the schema outlined in the study protocol.

Progress: Two patients have been entered on the study. One patient has responded extremely well but it is too early to report the status of the other.

Detail Summary Sheet

Date: 23 Oct 85 Proj No: POG 8346 Status: Ongoing
 Title: Comprehensive Therapy for Ewing's Sarcoma: Tailored versus Standard Radiation Therapy, Phase III.

Start Date 27 Mar 84	Est Comp Date:
Principal Investigator Terry E. Pick, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Ewing's sarcoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 14 December 1984 Results Continue	

Objective(s): To improve disease free survival in patients with Ewing's sarcoma utilizing a multidisciplinary approach.

Technical Approach: Patients with newly diagnosed, histologically verified Ewing's sarcoma are eligible. Patients must not have received previous chemotherapy or radiation therapy.

Therapy will follow the schema outlined in the study protocol.

Progress: One patient remains on the study.

Detail Summary Sheet

Date: 23 Oct 85	Proj No: POG 8370	Status: Ongoing
Title: Evaluation of Responses and Further Determination of Toxicity of Dibromodulcitol (DBD) in Children with Solid Tumors and Recurrent Brain Tumors Unresponsive to Standard Therapy, Phase II.		
Start Date 27 Jan 84	Est Comp Date:	
Principal Investigator	Facility	
Terry E. Pick, M.D., LTC, MC	Brooke Army Medical Center	
Dept/Svc	Associate Investigators:	
Department of Pediatrics		
Key Words:		
Solid tumors		
Accumulative MEDCASE	Est Accumulative	
Cost:	OMA Cost:	
Number of Subjects Enrolled During Reporting Period: _____		
Total Number of Subjects Enrolled to Date: _____		
Date of Periodic Review 14 December 1984 Results Continue		

Objective(s): 1) To determine the response rate and duration of response to DBD in children with advanced malignant disease including brain tumors unresponsive to conventional therapy.

2) To further determine the toxicity of DBD in children.

Technical Approach: Children less than 21 years of age with solid tumors including brain tumors and measurable lesions not amenable to standard therapy, with a life expectancy of more than three weeks who do not have an uncontrolled serious infection and who have an adequate nutritional status are eligible for the study.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered on this study.

Detail Summary Sheet

Date: 24 Oct 85 Proj No: POG 8426 Status: Ongoing
 Title: Intensive Chemotherapy (MOPP-ABVD) Plus Low Dose Total Nodal Radiation Therapy in the Treatment of Stages IIB, IIIB, IV Hodgkin's Disease in Pediatrics

Start Date 26 Mar 85	Est Comp Date:
Principal Investigator Terry E. Pick, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Hodgkin's disease	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____ Results _____	

Objective(s): 1) To determine the feasibility of Administering low dose TNRT to patients who have received 8 courses of MOPP-ABVD.

2) To determine the rapidity and completeness of clinical remission (CR) in patients treated initially by a non-cross resistant CT regimen, given in an alternating fashion, followed by reduced dose TNRT.

3) To determine the effect of combined modality therapy on splenic function as determined by the pitted erythrocyte count using Normarski optics.

Technical Approach: Patients <21 years of age, with histologically proven Hodgkin's disease, previously untreated with the exception of radiation therapy for airway obstruction or spinal cord compression, are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. No patients have been entered.

Detail Summary Sheet

Date: 24 Oct 85 Proj No: POG 8441 Status: Ongoing
 Title: Four Drug Combination Chemotherapy for Children with Stage D Neuroblastoma Older than 365 Days at Diagnosis - Phase III.

Start Date 22 Feb 85	Est Comp Date:
Principal Investigator Terry E. Pick, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Neuroblastoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 2	
Total Number of Subjects Enrolled to Date: 2	
Date of Periodic Review	Results

Objective(s): 1) To increase the incidence of long term disease-free interval in children \geq 1 year of age with the diagnosis of neuroblastoma Stge D disease treated with a multiagent regimen of cis-platinum, VM-26, cyclophosphamide and Adriamycin (CECA).

2) To determine the incidence of complete clinical response (CR) and surgical complete response after CECA.

3) To determine the acute and long-term toxicity of CECA.

Technical Approach: To be eligible, patients must be \geq 365 days and \leq 21 years of age at diagnosis and have received no chemotherapy or radiation therapy.

Therapy will follow the schema outlined in the study protocol.

Progress: Two patient have been entered into this study. No reportable data are available at this time.

Detail Summary Sheet

Date: 24 Oct 85 Proj No: POG 8451 Status: Ongoing
 Title: Intergroup Rhabdomyosarcoma Study III

Start Date 1 Feb 85	Est Comp Date:
Principal Investigator Terry E. Pick, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Rhabdomyosarcoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To compare various forms of therapy of rhabdomyosarcoma based on favorable and non-favorable histology.

Technical Approach: Patients under 21 years of age with the diagnosis of rhabdomyosarcoma or undifferentiated sarcoma, type indeterminate, or extraosseous Ewing's sarcoma, are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered on this study.

Detail Summary Sheet

Date: 23 Oct 85 Proj No: POG 8461 Status: Ongoing
 Title: Protocol for Initial Induction Failures in Childhood Acute Lymphoblastic Leukemia.

Start Date 25 Sep 84	Est Comp Date:
Principal Investigator Terry E. Pick, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Leukemia, lymphoblastic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): 1) To provide intensive, uniform therapy and determine toxicity, induction rate, and remission duration of this regimen.

2) To better characterize this unique subpopulation of patients with primary drug resistance by measurement of cell surface resistance associated protein and gene amplification of dihydrofolate reductase.

Technical Approach: Children and adolescents less than 21 years of age at diagnosis with acute lymphoblastic or undifferentiated leukemia meeting the criteria outlined in the protocol are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered on this study.

Detail Summary Sheet

Date: 23 Oct 85 Proj No: POG 8462 Status: Ongoing
 Title: ICRF-187 In Children with Solid Tumors or Acute Leukemia, Phase II

Start Date 31 May 85	Est Comp Date:
Principal Investigator Terry E. Pick, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Leukemia, acute	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____ Results _____	

Objective(s): 1) To determine the therapeutic efficacy of ICRF-187 in the treatment of children with leukemia or solid tumors.

2) To further determine the qualitative and quantitative toxicity in children given ICRF-187 daily for three days every three weeks.

Technical Approach: Eligible patients must be ≤ 21 years of age with histologic proof of malignancy (solid tumor or leukemia) not amenable to standard therapy, with a life expectancy of ≥ 4 weeks with measurable disease. Patients must be currently receiving no therapy and must have recovered from the toxic effects of all prior therapy.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered on this study.

Detail Summary Sheet

Date: 24 Oct 85	Proj No: POG 8464	Status:
Title: Phase II Study of Carboplatin in the Therapy of Children with Progressive Brain Tumors		

Start Date 31 May 85	Est Comp Date:
Principal Investigator Terry E. Pick, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Brain tumor	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____ Results _____	

Objective(s): 1) To determine the effectiveness of carboplatin (CBCDA) in the treatment of children with brain tumors unresponsive to standard therapy.

2) To further evaluate the toxicities of carboplatin in children.

Technical Approach: All patients <21 years of age diagnosed with a recurrent or progressive brain tumor who have slides of the original tumor for neuropathological review will be eligible for entry. The patient must have an estimated survival in excess of two months and a minimum Karnofsky performance score of 30%.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. No patients have been entered.

Detail Summary Sheet

Date: 24 Oct 85 Proj No: POG 8493 Status: Ongoing
 Title: Infant Leukemia Protocol

Start Date 26 Mar 85	Est Comp Date:
Principal Investigator Terry E. Pick, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Leukemia	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____ Results _____	

Objective(s): 1) To establish the qualitative and quantiative toxicity of this regimen in infants and to determine criteria for dose modifcaiton in infants.

2) To obtain an estimate of survival and disease-free survival in infants <12 months of age treated with intensive chemotherapeutic regimen.

Technical Approach: Patients with ALL (or undifferentiated leukemia) <12 months of age at diagnosis are eligible. All patients must comply with immunologic and cytogenetic criteria for diagnosis according to POG front line ALinC classification studies and must be registered on that study as well as this protocol.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. No patients have been entered.

Detail Summary Sheet

Date: 24 Oct 85 Proj No: POG 8495 Status: Ongoing
 Title: A Phase I Study of Hyperfractionation in Brain Stem Gliomas in Children

Start Date 26 Oct 84	Est Comp Date:
Principal Investigator Terry E. Pick, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Glioma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): 1) To test the feasibility of treating children with brain stem gliomas with hyprfractionated (twice daily) radiotherapy.

- 2) To study the immediate and late side effects of such treatment
- 3) To test the feasibility of escalation of the dose of radiotherapy in this situation.
- 4) To monitor the response of the patients in terms of tumor regression, disease free interval, and length of survival.

Technical Approach: Patients ≥ 3 and ≤ 21 years of age with a previously untreated tumor arising in the mesencephalon, pons, including the cerebellar peduncles and floor of the IVth ventricle, and medulla oblongata and with a life expectancy of greater than 6 weeks, shall be eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered into the study.

Detail Summary Sheet

Date: 24 Oct 85 Proj No: POG 8532 Status: Ongoing
 Title: Treatment of Intracranial Ependymomas

Start Date 31 May 85	Est Comp Date:
Principal Investigator Terry E. Pick, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Ependymoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review _____	Results _____

Objective(s): To estimate the occurrence of subarachnoid seeding in children with well differentiated, IVth ventricular ependymoma following resection and posterior foss irradiation.

Technical Approach: Patients ≥ 24 months and ≤ 21 years with histologically confirmed primary intracranial ependymomas or ependymoblastoma are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. No patients have been entered.

Detail Summary Sheet

Date: 24 Oct 85 Proj No: POG 8552 Status: Ongoing
 Title: A Case-Control Study of Childhood Rhabdomyosarcom

Start Date 31 May 85	Est Comp Date:
Principal Investigator Terry E. Pick, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Rhabdomyosarcoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	
Total Number of Subjects Enrolled to Date:	
Date of Periodic Review	Results

Objective(s): 1) To evaluate the relationships between environmental exposures and childhood rhabdomyosarcoma (RMS).
 2) To evaluate associations between gestational factors and childhood RMS.
 3) To evaluate the role of genetic factors in the etiology of childhood RMS.
 4) To develop new methods for using subjects from collaborative cancer clinical trials for etiologic research.

Technical Approach: This is a case-control study of childhood RMS which will identify its cases from a large national collaborative clinical trial. The study will reexamine several promising hypotheses suggested by the preliminary study of RMS.

Progress: No entries have been made into this study.

Detail Summary Sheet

Date: 24 Oct 85 Proj No: POG 8561 Status: Ongoing
 Title: Phase II Study of 6-Mercaptopurine Administered as an Intravenous
 Infusion for Malignant Solid Tumors and Acute Leukemia

Start Date 2 Aug 85	Est Comp Date:
Principal Investigator Terry E. Pick, M.D., LTC, MC	Facility Brooke Army Medical Center
Dept/Svc Department of Pediatrics	Associate Investigators:
Key Words: Solid Tumors Acute leukemia	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	
Total Number of Subjects Enrolled to Date:	
Date of Periodic Review	Results

Objective(s): 1) To determine response rate of children with advanced malignatn disease for whom no effective anti-cancer therapy is known to treat-
 ment with 6-mercaptopurine (6-MP) administered as a 48 hour IV infusion.

2) To further assess the toxicity in a larger group of children.

Technical Approach: Patients must be \leq 21 years of age with a measurable solid tumor or acute leukemia with either an M3 marrow or extra medullary disease. The diagnosis must be confirmed by appropriate histologic examination.

Progress: This is a new study. No patients have been entered.

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